"IDENTIFICATION OF RISK FACTORS ASSOCIATED WITH INFERTILITY AND THE EFFECT OF SUPPORTIVE INTERVENTION ON QUALITY OF LIFE AMONG WOMEN WITH PRIMARY INFERTILITY IN SELECTED HOSPITALS, PUDUCHERRY, A RANDOMIZED CONTROL TRIAL"

Thesis

submitted for the Award of the Degree of

DOCTOR OF PHILOSOPHY

IN NURSING

Faculty (Nursing)

Submitted to

SRI BALAJI VIDYAPEETH (Deemed to be University)

Accredited by NAAC with A^{++} Grade

by

Mrs. PON PRINCESS MANO

UIN NO: 2005002006

Under the guidance of

Prof. Dr. SUJATHA. T

Guide/ Convener Faculty (Nursing)

SHRI SATHYA SAI COLLEGE OF NURSING,
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PILLAIYARKUPPAM, PUDUCHERRY – 607402, INDIA.

March-2025

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viii.	Published article/Research visibility

ABSTRACT

A reproductive illness known as infertility is characterized by the inability to conceive a healthy child after 12 months or more of consistent, unprotected sexual activity.[2] Infertility affects an estimated 1 in 7 couples in the United Kingdom. In a year, 80% of couples who are attempting to get pregnant will succeed. Ninety percent of couples who are unable to conceive in the first year will do so in the second, for a total pregnancy rate of half in two years.[1.]

OBJECTIVES

The study aimed to identify the risk factors associated with infertility among the women with primary infertility, and to determine the effect of the supportive intervention on the quality of life among women with primary infertility in the study group.

METHODS

A Randomized control design was used to select the participants according to the inclusion criteria. A total of 192 Participants were assigned to study group and control group. The study group had direct counselling followed by Heartfulness Relaxation and Meditation, which was guided by the researcher for 4 consecutive weeks, 15-20 minutes/ day for 6 days. A structured interview schedule was used to assess the risk factors of infertility. The FertiQol standardized tool was used to assess the quality of life among women for both the study group and control groups. Recording of responses was done simultaneously. Observation and follow-up was done through WhatsApp and phone calls. The participants were asked to maintain an activity chart for 4 weeks for follow-up. Post-assessment was done after 4 weeks using the FertiQol scale to evaluate the Quality of life before and after the intervention in both groups.

RESULT

The present study proved that there was a statistically significant improvement in all aspects of quality of life after the intervention at $p< 0.001$, in all the aspects, with the mean difference in Emotional 5.34,($t==58.840, p<0.001^*$), Mind &Body:17.53,($t=51.474, p<0.001^*$), Relational:17.73, ($t=81.558, p<0.001^*$), and Social:10.1, ($t=46.919$, $p<0.001$), Treatment environment:10.67,($t= 55.136, p<0.001^*$), Treatment tolerability: 8.93, ($t=46.201$, $p<0.025^*$).

CONCLUSION

The study findings show that providing appropriate support can have a significant positive impact on the well-being of women struggling with infertility. By recognizing and addressing risk factors such as gynaecological factors, lifestyle factors, and psychological factors interventions can help to improve mental health, emotional resilience, and overall quality of life for infertile women.

CHAPTER - I

INTRODUCTION

1. BACKGROUND OF THE STUDY

Fertility is crucial for a woman. In our culture, having children is very important for couples. The feeling of becoming pregnant is amazing, and the mother is filled with joy when she feels her baby kick for the first time inside her belly.[1]Infertility is a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after the 12th month or more of regular unprotected sexual intercourse.[2] Infertility affects an estimated 1 in 7 couples in the United Kingdom. In a year, 80% of couples attempting to get pregnant will succeed. Ninety percent of couples unable to conceive in the first year will do so in the second, for a total pregnancy rate of half in two years.[1.]

Infertility is a global health issue affecting millions of people of reproductive age worldwide. Available data suggests that between 48 million couples and 186 million individuals have infertility globally. Due to population growth, however, the absolute number of couples affected by infertility increased from 42.0 million (39.6 million, 44.8 million) in 1990 to 48.5 million (45.0 million, 52.6 million) in 2010.[3]

According to World Health Organization estimate the overall prevalence of primary infertility in India is between 3.9 to 16.8%. In Indian states, the prevalence of infertility varies from state to state such as 3.7 percent in Uttar Pradesh, Himachal Pradesh, and Maharashtra, to 5 percent in Andhra Pradesh, and 15 percent in Kashmir and prevalence varies in the same region across tribes and caste.[4]

Ashwini Katole Department of Community Medicine (2019) conducted a community-based cross-sectional study in Nagpur, Maharashtra, The Prevalence of Primary Infertility and its Associated Risk Factors in Urban Population of Central India.[5]

The result shows that the overall prevalence of primary infertility among reproductive age group women was 8.9% (51/570). Sociodemographic factors that had a statistically significant association with infertility were age at marriage of more than 25 years ($P < 0.05$), nuclear family, higher education level, employed women, high socioeconomic status, and family history of infertility. Physiological factors that had a statistically significant association with infertility were obesity, age at menarche of more than 14 years, and irregular menstruation pattern. Depression and stress were the psychological factors significantly associated with infertility. So the study concluded that the prevalence rate of primary infertility in an urban

population of Central India was lower than reported trends of infertility from developing countries.[5]

A Comparative Study was conducted by Nigesh Kalorath, and Tilottama Mukherjee (2020), to compare the psychological factors that may play a role in couples with and without infertility (30 infertile couples and 30 matched fertile couples) research identified several psychological dimensions related to fertility. But Stress was not considered. No intervention was given.[6]

In addition to physical support, infertile women require mental and psychological support, to improve fertility outcomes, mental health, and quality of life. Healthcare providers and Midwives have a greater role in counselling women along with reproductive care to clients with a history of infertility. The researcher has taken the coaching method of counselling, Heartfulness relaxation, and meditation as a supportive intervention tool and assesses the effectiveness of the intervention to improve the quality of life of infertile women.

NOVELTY OF THE STUDY

Various studies have been done globally and nationally to state the prevalence, risk factors, treatment, and quality of life among infertile couples. However, very few studies are focused on interventions to improve the quality of life among women with infertility. The proposed research aims to determine the effect of mindfulness relaxation and Meditation, on the quality of life among infertile women.

1.2 AIM

To Identify the Risk Factors Associated with Infertility and the Effect of Supportive Intervention on Quality of Life among women with primary infertility.

1.3 OBJECTIVES

1.3.1 PRIMARY OBJECTIVES

- To identify the risk factors associated with infertility among the women with primary infertility in selected hospitals in Puducherry.
- To assess the quality of life before intervention among women with primary infertility in the study group and control groups in selected hospitals in Puducherry.
- To determine the effect of the supportive intervention on the quality of life among women with primary infertility in the study group.
- To find out the association between the quality of life among women with primary infertility in study group and control groups with selected demographic variables.

1.3.2 SECONDARY OBJECTIVES

- To assess the perceived level of satisfaction among women with primary infertility after the intervention.

1.4 OPERATIONAL DEFINITION

Infertility: Infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse

Women: In this study, it refers to a married female having an inability to conceive even after having unprotected and regular intercourse for one year

Primary infertility: It refers to couples who have not become pregnant after at least 1 year of having sex without using birth control methods.

Risk factors: These refer to the factors that could contribute to the cause of infertility which may include irregular menstrual cycle, marital life duration, ovarian and tubular diseases, marital and familial conflicts, lifestyle factors such as food habits other practices, sexual activity, etc.

Supportive intervention: It refers to therapeutic counselling provided by the researcher including coaching the clients to improve self-management strategies to cope with physical, emotional, family, and social stress related to infertility, Heartfulness relaxation, and meditation for four consecutive weeks, and aerobic exercise like walking, jogging, skipping, cycling.

Heartfulness relaxation and meditation: Heartfulness meditation is a form of meditation that places primary focus on the heart, encouraging practitioners to connect with their inner essence and develop a deep sense of love and compassion. The researcher will guide the participant through series of instructions to get relaxed and conscious about their inner strength and carry them through meditation for 20 minutes through prerecorded audio and video.

Aerobic exercises: Aerobic exercise is a physical activity that increases the heart rate and oxygen uptake by the body to produce energy. The participant can choose which ever form is comfortable for her walking, jogging, skipping and cycling.

Quality Of Life: It refers to the perception of women with infertility regarding their position in life, in which an individual is healthy, comfortable, and able to participate in and enjoy life events.

1.5 HYPOTHESES

1. **H_1 -** There will be a significant difference in the quality of life of the women with primary infertility before and after the intervention among infertile women in the experimental group.
2. **H_2-** There will be a significant association between the quality of life among women with primary infertility in experimental and control groups with selected demographic variables.

1.5.1 ASSUMPTIONS

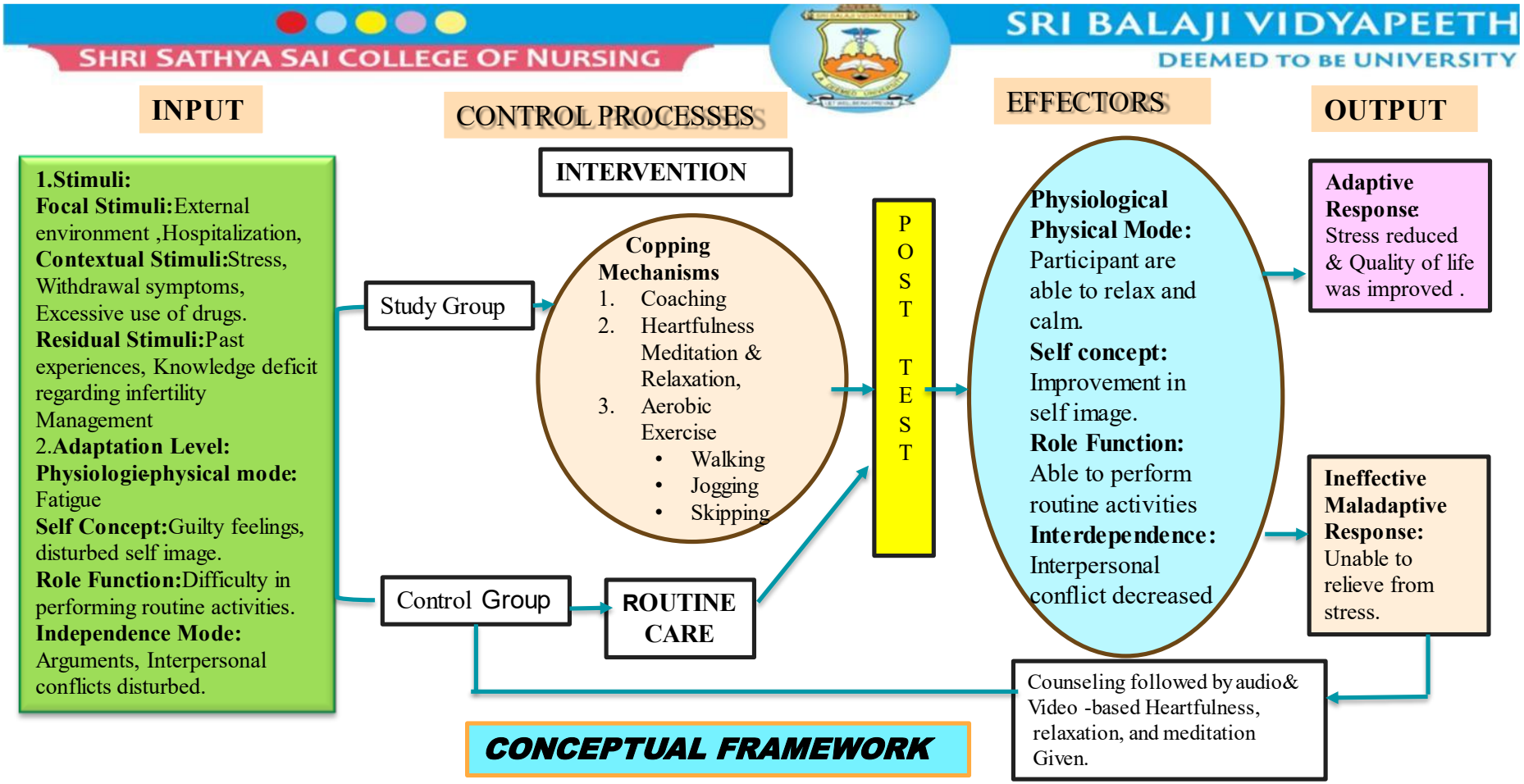
The study assumed that –

- Women will have the stress of infertility treatment
- Supportive intervention will reduce stress and improve the Quality of life

1.5.2 DELIMITATIONS

- The study is delimited by women with primary infertility
- The study is delimited to a period of 1 year

1.4.1. CONCEPTUAL FRAMEWORK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INPUT
CONTROL PROCESSES
EFFECTORS
OUTPUT
1.Stimuli:
Focal Stimuli:External environment ,Hospitalization,
Contextual Stimuli:Stress, Withdrawal symptoms, Excessive use of drugs.
Residual Stimuli:Past experiences, Knowledge deficit regarding infertility Management
2.Adaptation Level:
Physiologiephysical mode: Fatigue
Self Concept:Guilty feelings, disturbed self image.
Role Function:Difficulty in performing routine activities.
Independence Mode: Arguments, Interpersonal conflicts disturbed.
INTERVENTION
Study Group
Copping Mechanisms
1. Coaching
2. Heartfulness Meditation & Relaxation,
3. Aerobic Exercise
• Walking
• Jogging
• Skipping
Control Group
ROUTINE CARE
POST TEST
Physiological Physical Mode: Participant are able to relax and calm.
Self concept: Improvement in self image.
Role Function: Able to perform routine activities
Interdependence: Interpersonal conflict decreased
Adaptive Response Stress reduced & Quality of life was improved .
Ineffective Maladaptive Response: Unable to relieve from stress.
Counseling followed by audio& Video -based Heartfulness, relaxation, and meditation Given.
CONCEPTUAL FRAMEWORK

Fig 1: Effect of Supportive Intervention on Quality of Life among women with Primary Infertility Based on MODIFIED CALISTA ROY ADAPTATION THEORY - 1976

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CHAPTER - II

REVIEW OF THE LITERATURE

The review of the literature is organized under the following sections.

Section I: Literature related to risk factors associated with infertility.

Prevalence of Primary Infertility and its Associated Risk Factors In a community-based cross-sectional study, conducted by Ashwini Katole in 2019 all married women between 15 and 49 years of age in urban field practice area were included. The objective of the study is (1) to estimate the prevalence of primary infertility among women of reproductive age group in an urban population of Central India and (2) to study its associated risk factors. Results show that the overall prevalence of primary infertility among reproductive age group women was 8.9% (51/570). Sociodemographic factors that had a statistically significant association with infertility were age at marriage more than 25 years, nuclear family, higher education level, employed women, high socioeconomic status (P = 0.01), and family history of infertility. Physiological factors that had a statistically significant association with infertility were obesity, age at menarche of more than 14 years, and irregular menstruation pattern, Depression and stress were the psychological factors significantly associated with infertility. The study concluded that the prevalence rate of primary infertility in an urban population of Central India was lower than reported trends of infertility from developing countries.[5]

This cross-sectional study was conducted By Azam Moridi in 2019,in infertility centers of Hormozgan University of Medical Science (HUMS). to investigate the etiology and risk factors associated with infertility in the southern region of Iran. 250 infertile couples were included. The result shows that the most common causes of male and female infertility were varicocele (49.4%) and ovulation disorders (57.5%), respectively. There was a significant association between female factor infertility and level of education, age of women, women's age at marriage, number of abortions, alcohol consumption, presence of an underlying disease, and BMI (P<0.005) There was also a significant relationship between male factor infertility and men's job, addiction, smoking, and presence of an underlying disease, Study conclude that Considering various risk factors for infertility, an important step forward can be taken towards reducing the incidence of these risk factors by providing different education**.**[7]

Section II: Literature related to supportive intervention to improve the quality of life of women with infertility.

A study was done to examine the influence of infertility on the psychological health of women. 150 infertile and 150 fertile women from Faisalabad, Pakistan were included in the study. Data were compiled with a Brief Interview Form (BIF) and Psychological Wellbeing Scale. Results showed that the Infertile women significantly reported less autonomy (t = -15.56, df=298, p=0.000), environmental mastery (t=- 10.378, df=298, p=0.000), personal growth (t=-9.403, df=298, p=0.000), purpose in life (t = -7.786, df=298, p=0.000) and self-acceptance (t = - 12.93, df=298, p=0.000) but more positive relation with others (t=3.44, df=298, p=0.001) than fertile women. The study concluded that infertility is a significant risk factor for psychological well-being of infertile women.[8]

A study was done to evaluate the effect of a mindfulness-Based Program for Infertility (MBPI). Fifty-five women attended the MBPI sessions and completed self-report measures of depression, anxiety, mindfulness, and experiential avoidance at post-MBPI (T1), 6-month follow-up (T2), and 7-year follow-up (T3). There were significant direct time effects regarding experiential avoidance ($F = 3.81$; $p < 0.033$; $\eta p2 = 0.08$), the mindfulness facets describing ($F = 3.54$; $p = 0.037$; $\eta p2 = 0.13$), acting with awareness ($F = 6.87$; $p = 0.002$; $\eta p2 = 0.22$), nonjudging of inner experience ($F = 10.66$; $p < 0.001$; $\eta p2 = 0.31$), and depressive symptoms ($F = 4.85$; $p = 0.020$; $\eta p2 = 0.10$). There was an increase in the describing facet from T1 to T3 ($p = 0.036$). The act with awareness facet increased from T1 to T2 ($p = 0.010$) and from T1 to T3 ($p = 0.007$), as well as the nonjudging of inner experience facet (T1 to T2 [$p = 0.030$] and T1 to T3 [$p = 0.002$]). Experiential avoidance decreased from T1 to T3 ($p = 0.022$) and depressive symptoms from T1 to T2 ($p = 0.019$). Post-MBPI scores were maintained at T2 and T3 concerning anxiety symptoms and the observing and no-reactivity mindfulness facets. There were long-term effects of MBPI on mindfulness and experiential avoidance. Moreover, therapeutic gains were maintained regarding depression and anxiety symptoms, independently of the reproductive outcome.[9]

2.1 RESEARCH GAP

- Various studies have been done to find the prevalence of risk factors for infertility but very few global studies & no study in India addressed on the interventions on risk factors of infertility
- Extensive research of 25 studies on infertility during last five years was reviewed from Pubmed, Scopus, Web of Science, Google Scholar, among them 13 studies

focussed on quality of life among infertile couples, among them 8 no of studies focussed on some kind of supportive therapies that will help with coping strategies for the stress related to infertility treatment. None of the studies was done to determine the effect of supportive intervention to improve the quality of life.

CHAPTER - III

RESEARCH METHODOLOGY

3.1 RESEARCH APPROACH

Quantitative approach.

3.2 RESEARCH DESIGN

Randomized block design (True experimental research design).

3.3 RESEARCH VARIABLES

Independent variable: Supportive intervention (Coaching, mindfulness relaxation, and Meditation, Aerobic exercise like walking, jogging, skipping, and cycling.)

Dependent variable: Quality of Life of the women with primary infertility

Demographic variables: It includes socio-demographic variables like age, religion, occupation, type of family, marital status, family income, occupation, Source of income, and Residence. Years of married life.

Clinical Variables: Gynaecological factors which include menstrual history, marital history, and Family history. Psychological factors include h/o marital conflicts, and familial conflict. Lifestyle factors as diet, exercise, habits, and sexual activity, Documentation schedules like Body mass index, Hormonal factors, and Previous history of infertility.

3.4 RESEARCH SETTING

The study was conducted on the women attending infertility clinics at selected hospitals in Puducherry.

3.5 POPULATION

TARGET POPULATION: The population of the present study comprises all Women with primary infertility.

ACCESSIBLE POPULATION

All Women with primary infertility aged between 21 to 45 years attending selected hospitals in Puducherry.

SAMPLE: Women in the age group of 21-45 years with primary infertility meeting the inclusion criteria.

3.6 SAMPLING TECHNIQUE: Randomized block design.

Since several blocks in randomization are 4, the sample size was increased to 172. (170 is not divisible by 4 and 172 is the next integer divisible by 4). With the help of a statistician, included a 10% attrition rate in determining the sample size. With 10 % attrition, the calculated sample size was 192.

3.7 SAMPLE SIZE: The estimated sample size was192 (96 in each group)

3.8 SAMPLING CRITERIA

INCLUSION CRITERIA

- Women in the age group of 21-45 years with primary infertility
- Women who are willing to participate

EXCLUSION CRITERIA

- Women with secondary infertility

WITHDRAW CRITERIA

Participants can withdraw from the study at any time if they feel uncomfortable and cannot cooperate with the study.

3.9 DATA COLLECTION TOOL

<table>
<tr><th>TOOL</th><th>DESCRIPTION</th><th>INFERENCE</th></tr>
<tr><td>Section A
Interview Scheduled</td><td>Part I: It consist of the Demographic variables including age, religion, education, occupation, breadwinner , family type, income and place of residence, reason for infertility
Part II: It consist of gynaecological factors which include menstrual history, marital history, and Family history
Part III: It consists of Psychological factors including h/o marital conflicts, familial conflict.
Part IV : It consist of Lifestyle factors as diet , exercise, habits and sexual activity
Part V: Documentation schedules like Body mass index, Hormonal factors, Previous history of infertility.</td><td></td></tr>
<tr><td>Section B
Fertility Quality of Life Questionnaire standardize tool used to assess the Quality of Life among infertile women.</td><td>
<table>
<tr><th colspan="6">RESPONSES</th></tr>
<tr><td>S.No</td><td>0</td><td>01</td><td>02</td><td>03</td><td>04</td></tr>
<tr><td>Scale 1</td><td>Very Poor</td><td>Poor</td><td>Neither poor nor Good</td><td>Good</td><td>Very Good</td></tr>
<tr><td>Scale 2</td><td>Very Dissatisfied</td><td>Dissatisfied</td><td>Neither satisfied nor Dissatisfied</td><td>Satisfied</td><td>Very Satisfied</td></tr>
<tr><td>Scale 3</td><td>Always</td><td>Very Often</td><td>Quite often</td><td>Seldom</td><td>Never</td></tr>
<tr><td>Scale 4</td><td>An extreme amount</td><td>Very much</td><td>Moderate amount</td><td>A little</td><td>Not at all</td></tr>
<tr><td>Scale 5</td><td>Completely</td><td>A great deal</td><td>moderately</td><td>Not much</td><td>Not at all</td></tr>
</table>
</td><td>Score is graded as,
➢ 1-50 =<50% - Low
➢ 50-75 = 50 - 75% - Better
➢ >75 = >75% - Good</td></tr>
<tr><td>Section C
Interview Schedule</td><td>To assess the perceived level of satisfaction among women with primary infertility after the intervention</td><td>< 12=<50% - Low Satisfaction,
13-18=51-75% - Moderate Satisfaction,
19-24=>75 -100%- High Satisfaction</td></tr>
</table>

3.10 VALIDITY OF THE TOOL

The study was discussed in the research advisory committee and approved. The suggestions were incorporated and later sent for validation from external experts. Content validity was obtained from 2 Obstetricians, 7 nursing experts, and 1 psychologist. Suggestions given by the experts were incorporated into the main study.

3.11 RELIABILITY OF THE TOOL

The instruments used in the study are more standardized and widely used in many types of research, The Fertility Quality of Life (FertiQoL) tool has satisfactory reliability, with Cronbach reliability statistics ranging from 0.72 to 0.92

3.12 PILOT STUDY

The Pilot study was conducted in OBG OPD at Pondicherry Institute of Medical Sciences and St. Joseph Cluny Hospital, Puducherry. After ensuring the validity and reliability of the tool, among 30 women with primary infertility (15 Study Groups, 15 Control Groups). It was recommended to include Women with Primary infertility Aged between 21 to 45 years for the, during the September 2022 to Dec 2022.The tools was found feasible and appropriate.

3.13 DATA COLLECTION PROCEDURE

1. A prior Formal administrative permission is obtained from the Director- Principal, IRB, Ethical Committee HOD OBG Department Pondicherry Institute of Medical Sciences and St. Joseph Cluny Hospital, Puducherry. And concerned authorities at the time of data collection.
2. A random sampling method selected based on the inclusion criteria. Informed consent was taken from the participant before collecting data.

Phase 1:

1. Pre-assessment of risk factors for infertility using a structured questionnaire for both samples

2. Assessment of QOL of participants using the FertiQol standardized tool for both groups.

Phase 11:

Supportive intervention for study group

Day 1: Researcher did direct counselling (Coaching)

Section 1: Counselling on coping with infertility treatment

Section 2: Heartfulness relaxation and meditation

Section 3: Aerobic exercise

The researcher did direct counselling for 5 to 10 minutes with open communication, empathy, and active listening, on matters related to relationship difficulties, problems related to sex, personal issues, problems in adjusting to infertility or current life situations that may affect the couple's decision of treatment IVF. Counselling is followed by demonstration by the researcher on Heartfulness relaxation and Meditation. Participants were asked to Sit comfortably and close the eyes very softly and very gently and meditate for 15 to 20mts and follow the instructions of the researcher. After meditation, the participant can choose any one form of aerobic exercise which is comfortable for her (walking/ jogging, skipping/ cycling for 30 minutes). The participants were directed to do it regularly in the morning or evening. If the participant did Heartfulness, relaxation, and meditation in the morning then they have to do aerobic exercise in the evening when they feel comfortable.

Day 2 to Day 28, for 4 consecutive weeks

The study group participants followed audio-based Heartfulness, relaxation, and meditation using mobile and headphones/earphones every morning and aerobic exercise like, walking/ jogging, and skipping/ cycling for 30 minutes daily. The researcher followed the participant through WhatsApp and phone calls. Also, the participant maintained an activity chart which was verified by the researcher during the hospital visit supportive intervention was given to the control group. Day 28 post assessment of the quality of life using fertiQol Scale for both study and control group.

3.14 DROP OUT ANALYSIS

Table 3.1: Drop out analysis of the sample

ANALYSIS OF THE DROP OUTS IN FREQUENCY AND PERCENTAGE							
Group	No of Drop out	Percentage (%)	Reason	Group	No of Drop out	Percentage (%)	Reason
StudyGroup-(n=96)	1	1.04	Migrated	Control Group-(n=96)	1	1.04	Migrated
					1	1.04	Unable to contact
Total	1	1.04		Total	2	2.08	

*Dropouts are substituted, since it is in initial stage.

3.15 QUALITY ASSUARANCE OF THE INTERVENTION

Quality assurance of the intervention monitored by Sr. Dr. Mony. K, Principle at College of Nursing, PIMS

3.16 ETHICAL CONSIDERATION

The study was proposed in various Research Advisory Committee meetings and was revised. The study was also scrutinised for ethical concerns in the IEC/Pondicherry Institute of Medical Sciences, Puducherry (IEC:RC/2021/76). The study was also registered and approved by the highest regulatory authority CTRI. (CTRI/2022/05/042644).

Formal administrative permission was obtained from the Director-Principal, HOD OBG Department PIMS, St Joseph Cluny Hospital, Puducherry and concerned authorities at the time of data collection.

Participants were informed regarding the purpose of the study. Benefits were explained. Flexibility in withdrawal from the study was also ensured. Homogeneity was maintained with regard to the age in both groups.

SCHEMATIC REPRESENTATION OF THE RESEARCH METHODOLOGY

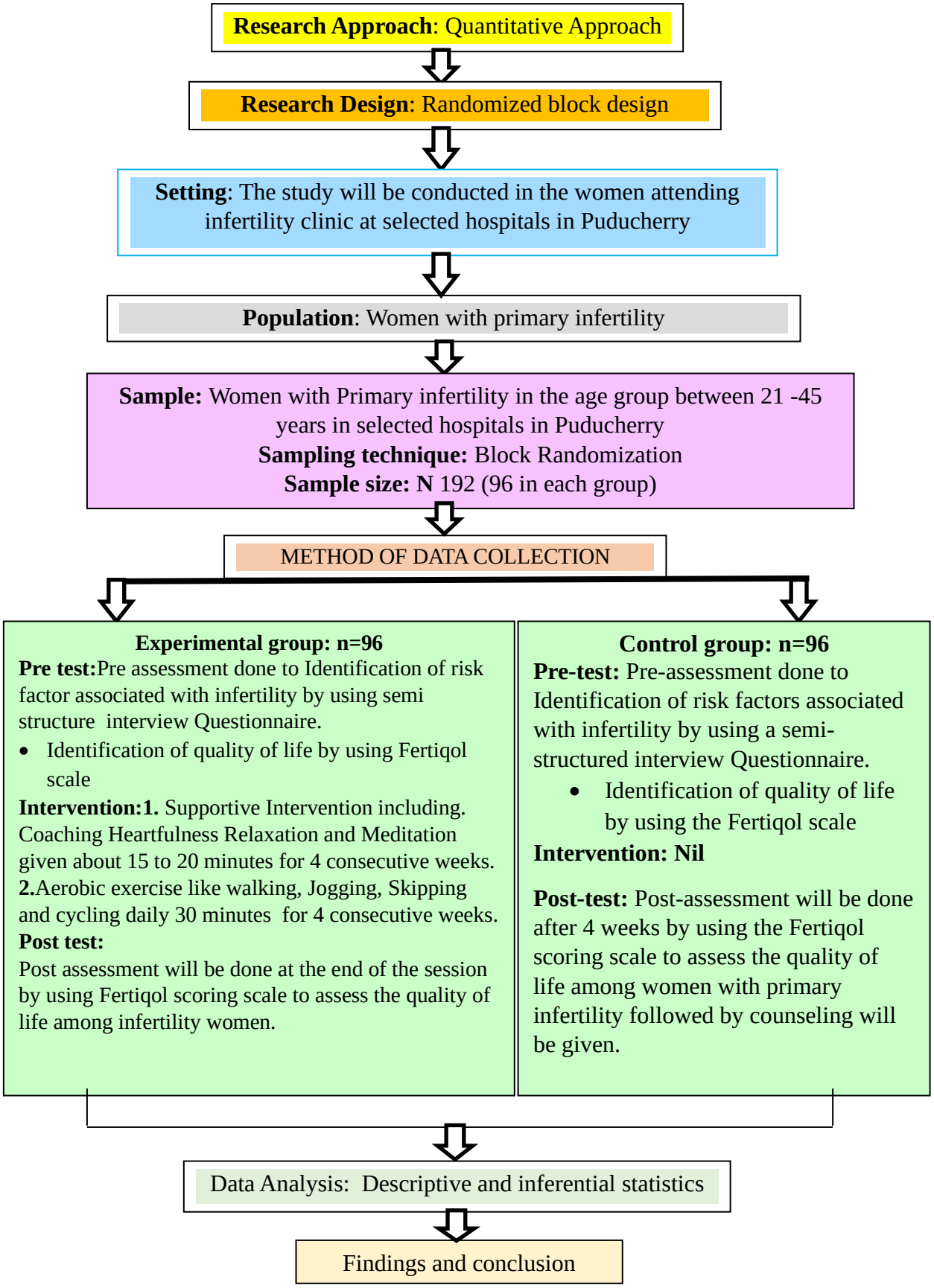
Research Approach: Quantitative Approach
Research Design: Randomized block design
Setting: The study will be conducted in the women attending infertility clinic at selected hospitals in Puducherry
Population: Women with primary infertility
Sample: Women with Primary infertility in the age group between 21 -45 years in selected hospitals in Puducherry
Sampling technique: Block Randomization
Sample size: N 192 (96 in each group)
METHOD OF DATA COLLECTION
Experimental group: n=96
Pre test:Pre assessment done to Identification of risk factor associated with infertility by using semi structure interview Questionnaire.
Identification of quality of life by using Fertiqol scale
Intervention:1. Supportive Intervention including. Coaching Heartfulness Relaxation and Meditation given about 15 to 20 minutes for 4 consecutive weeks.
2.Aerobic exercise like walking, Jogging, Skipping and cycling daily 30 minutes for 4 consecutive weeks.
Post test:
Post assessment will be done at the end of the session by using Fertiqol scoring scale to assess the quality of life among infertility women.
Control group: n=96
Pre-test: Pre-assessment done to Identification of risk factors associated with infertility by using a semi-structured interview Questionnaire.
Identification of quality of life by using the Fertiqol scale
Intervention: Nil
Post-test: Post-assessment will be done after 4 weeks by using the Fertiqol scoring scale to assess the quality of life among women with primary infertility followed by counseling will be given.
Data Analysis: Descriptive and inferential statistics
Findings and conclusion

Fig 2: Schematic Representation of the Research Methodology

CHAPTER - IV

DATA ANALYSIS & INTERPRETATION

DATA ANALYSIS

Data collected was analysed using IBM (International Business Machines Corporation) "Statistical Package for Social Sciences" (SPSS) software version 25.0. Data analysis was done based on the objectives of the study using descriptive and inferential statistics.

Sociodemographic variables

A total of 192 Primary infertility women were enrolled in the study.

Description of socio-demographic variables:

The majority 52(54%) of the participants were in the age group of > 30 years in the Study group as well as 54(56.3%) were in the Control group. Most of them were Hindu 81(84.4)%in the Study group and 77 (80.2%) in the control group of them had completed their secondary education in both groups 45 (46.9%)in the Study group 44 (45.8%) were in the control group, Most of them were housewives 45(49.0) in Study group and 47 (49.0%) were in the control group, and according to the income most of their family income was ≤ Rs.25,000, 52 (54.2) in the Study group and 56 (58.3%) in the control group. The family's breadwinner is the husband in Study Group 70 (72.9%) & control Group 71(74.0%).In terms of family type, majority of the families were nuclear type 74 (77.1%)in the Study group and 76 (79.2%)control groups with the residence majority 56 (58.3%)in the Study group & 60 (62.5%) in control group belonging to a rural area.The majority of the women 76 (79.2%) in the Study group, and 77(80.2 %) in the control group had infertility problem.

4.1 Objective 1: To identify the risk factors associated with infertility among the women with primary infertility in selected hospitals in Puducherry.

GYNAECOLOGICAL FACTORS:

Most of the participant had attained menarche at the age group of 13 – 15 years. The Pattern of occurrence of menstrual cycle was once in 33 – 45 days among 57 (59.4%) participants in the Study group and 52 (54.2%) participants in the control group. 56 (58.3) in the study group and 64 (66.7%) in the control group had 3-5 days of menstruation, Premenstrual symptoms were Rarely present in both groups and the type of marriage is Non

Consanguineous is 78(81.3%) among Study group and 80(83.3%)were in control group, with regard to Years of Marital life most of them were in the age between 4 - 6 years 63(65.6%) in Study group 64(66.7%)in control group.29(30.2%) were in the Study group and 30(31.3%) in the control group having DM.

PSYCHOSOCIAL FACTORS

According to the Psychosocial factors , 58 (60.4%) women in study group and 59 (61.5%) in the control group had marital conflict's, 58 (%60.4) participants in the Study group 57 (59.4%) were in the control group. There was no sufficient income to run your family 72 (75.0%) in Study group & 72 (75.0%) in the control group. Most of the spouses were caring towards their wives yet 36 (37.5%) in the control group were not caring. Both groups of women have job & social stress.

LIFESTYLE FACTORS

In lifestyle factors, most of them were non-vegetarian. Frequency of meals regularly 3 meals in both groups 71 (74.0%)in the Study group & 68 (70.8%) in the control group were having regular 3 meals, Majority of them having a food habit of nonvegetarian but 15 (15.6%) taking junk foods in the Study group and 15 (15.6 %)in the control group. According to the type of exercise most of them were doing household work 65 (67.7%) in both the Study group and control groups, and some of them were going walking 31(32.3%) in both group, There were no personal habits in either group. 53 (55.2 %) in the control group there is no Exposure to passive smoking 43 (44.7%) in the Study group, 31(32.35%) participants in the Study group and 32 (33.3%) participant's in control group had Once a week coitus 14 (14.6%) participants in Study group and 12 (12.5%) participants in control group, were not using any contraceptive methods.

DOCUMENTATION SCHEDULE

According to the BMI, most of them had 51(49.50%) in the Study group 52(50.50%) in the control group had normal weight, 8(57.10 %) in the Study group and 6(42.90%) in the control group were obese. The majority of them 41(42.7%) in Study Group 46(47.9%) in the control group had Polycystic ovarian disease, Most of them 76(79.2%) in Study Group 77(80.2%) were in the control group had prolactin imbalance, all the participant had undergone Previous fertility treatment.

Table 4.1: Distribution of participant according to the risk factors associated with infertility among women with primary infertility N=96+96=192

Variables	Odds Ratio	95% C. I		p-value
		Lower	Upper	
Dysmenorrhoea	1.218	0.428	3.464	0.712
Age at marriage	1.251	0.49	3.192	0.64
Type of marriage	1.449	0.564	3.727	0.441
Marital conflicts	25.159	2.299	275.318	0.008*
Conflicts In-Laws	1.167	0.556	2.447	0.683
Income not sufficient	1.433	0.498	4.128	0.505
Lack of Spouse care	30.499	3.02	308.005	0.004*
Frequency of meals	1.035	0.488	2.193	0.929
Food habits	1.162	0.37	3.647	0.798
coitus	1.287	0.131	12.621	0.828
Hormonal Imbalance	1.136	0.331	3.898	0.84

Note:*p-values less than 0.05

Table 4.1: The above table shows that **Marital conflicts (**OR25.159, 95% CI) **and a lack of spousal care (**OR30.499, 95% CI) are significant risk factors. Other factors include dysmenorrhoea, age at marriage, type of marriage, Conflict with laws, insufficient income, frequency of meals, food habits, frequency of coitus hormonal Imbalance shows some association, but they are not statistically significant.

4.2 Objective 2: To assess the quality of life before intervention among women with primary infertility in experimental and control groups in selected hospitals in Puducherry.

Table 4.2: Distribution of quality of life before intervention among women with primary infertility in the study group and control group

N=96+96=192

Variable	Pre-test Control Group		Pre-test Experimental		MD	T-test	p-value
	Mean	SD	Mean	SD			
Emotional	4.56	1.263	5.11	1.16	0.55	-3.54	0.002
Mind/body	2.94	1.575	3.81	2.368	0.87	-3.015	0.003
Relational	4.16	1.173	4.58	1.228	0.42	-2.464	0.015
Social	13.13	0.976	12.21	1.222	0.92	5.743	0.0001
Treatment environment	11.93	0.771	11.73	1.051	0.2	1.488	0.139
Treatment tolerability	5.82	0.768	5.95	1.118	0.13	-0.903	0.368

*Statistically significant at p 0.001

Table 4.2: The mean difference in pre-test value for the control group and Study group, in Emotional MD 0.55, (t=-3.54p <0.002), Relational MD 0.42,(t=-2.464,p<0.015), Treatment environment MD 0.2,(t=1.488p<0.139), Treatment tolerability MD 0.13(t=-0.903,p<0.368)**.**Only Mind &Body MD0.87,(t=-3.015, p<0.003*) and Social MD 0.92, (t=5.743,p<0.001*)**.** Hence it proved that there was no statistically difference in some aspects of quality of life before intervention in the Study group and control group.

4.3 Objective 3: To determine the effect of the supportive intervention on the quality of life among women with primary infertility in the study group.

Table 4.3: Compare the Mean & standard deviation of pre and post-test scores of the Study group and the Quality of life of women with primary infertility.

N=96+96=192

FertiQol Scale	Group	Test	Mean	S.D	MD	T-test	P value
Emotional	Study group	Pre Test	5.11	1.16	15.34	58.840	p<0.001*
		Post Test	20.45	2.375			
Mind & Body	Study group	Pre Test	3.81	2.368	17.53	51.474	p<0.001*
		Post Test	21.34	1.64			
Relational	Study group	Pre Test	4.58	1.228	17.73	81.558	p<0.001*
		Post Test	22.31	1.767			
Social	Study group	Pre Test	12.21	1.222	10.1	46.919	p<0.001*
		Post Test	22.31	1.894			
Treatment environment	Study group	Pre Test	11.73	1.051	10.67	55.136	p<0.001*
		Post Test	22.4	1.883			
Treatment tolerability	Study group	Pre Test	5.95	1.118	8.93	46.201	p<0.025*
		Post Test	14.88	1.446			

*****Statistically significant at p 0.001

Table 4.3: P value was p< 0.001*, in all the aspects, with the mean difference in Emotional (15.34), Mind & Body (17.53), Relational (17.73), and Social (10.1). Treatment environment (10.67), Treatment tolerability (8.93). Hence it proved that there is a statistically significant improvement in all aspects of quality of life after the intervention.

N=96+96=19

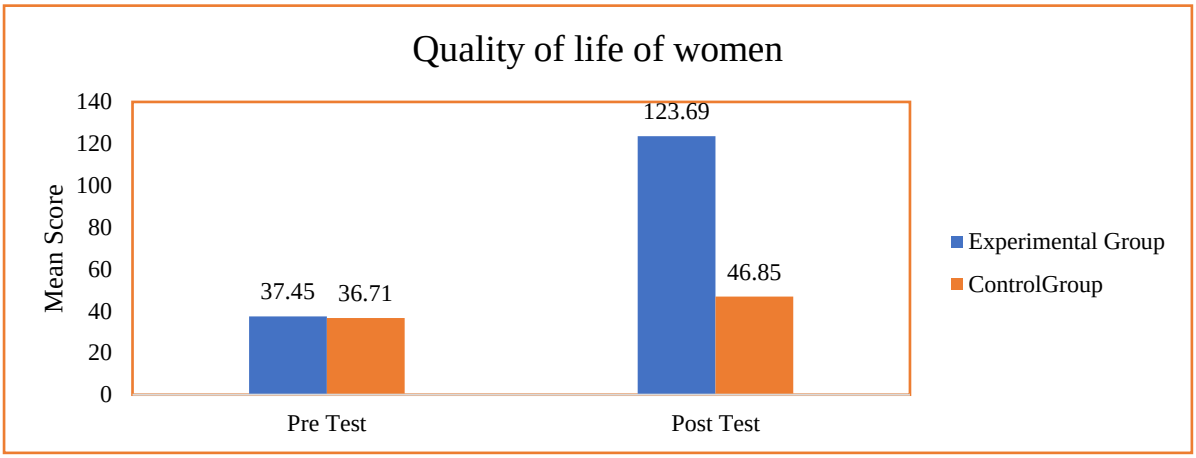

Figure 3: Compare the Pre and post-test scores of the quality of life of participants in the Study group and control group.

The above figure shows that the total mean score of the Study group after the intervention is 123.69 higher than the pre-test score so the quality of life improved after the intervention.

4.4 Objective 4: To find out the association between the quality of life among women with primary infertility in experimental and control groups with selected demographic variables.

Table : 4.4.1 Part- I: Association between the quality of life among women with primary infertility in the Study group & control groups with selected demographic variable.

N=96+96=192

SL.NO	DEMOGRAPHIC VARIABLES	P Value
1.	Age (in years)	0.78
2.	Religion	0.65
3.	Educational status	0.66
4.	Occupation	0.99
5.	Income	0.75
6.	Breadwinner of your family	0.87
7.	Type of family	0.72
8.	Residence	0.55
9.	Reason for infertility	0.45

Note P< 0.001* Statistically significant

Table 4.4.1 : There is no association between the quality of life among women with primary infertility in the Study group & control groups with selected socio-demographic variables like Age, gender, religion, educational status, occupation, Income, the breadwinner of the family, type of family, residence and the reason for infertility.

Table:4.4.2 Part- II: Association between the quality of life among women with primary infertility in Study group & control groups with Risk factors associated with primary infertility N=96+96=192

SL.NO	Gynaecological factors	P Value
1.	The pattern of occurrence of the menstrual cycle	0.45
2.	Days of menstrual flow	0.45
3.	Premenstrual symptoms	0.57
4.	Age at marriage	0.57
5.	Type of marriage	0.57
6.	Years of Marital Life	0.99
7.	Inherited conditions	0.87
Psychological factors		
1.	Marital conflicts	0.88
2.	Conflicts with In-Laws	0.88
3.	Income sufficient to run your family	0.55
4.	Spouse caring towards you	0.16
Lifestyle factors		
1.	Type of food	0.87
2.	Frequency of meals	0.62
3.	Food habits	0.98
4.	Type of exercise do you practice	0.99
5.	Exposed to passive smoking	0.99
6.	How often do you have coitus?	0.97
Other factors		
1.	Body mass index	0.93
2.	Diagnosed cause of infertility	0.85
3.	Hormonal imbalance	0.99

Note: P< 0.001*Statistically significant

Table 4.4.2 : There is no association between the quality of life among women with primary infertility in the Study group & control groups with selected clinical variables like Gynaecological factors, Psychological factors, lifestyle factors and others factors are Body mass index, Diagnosed cause of infertility, Hormonal imbalance.

4.5 Objective 5

Perceived level of satisfaction among women with primary infertility in study group after the intervention.

N=96+96=192

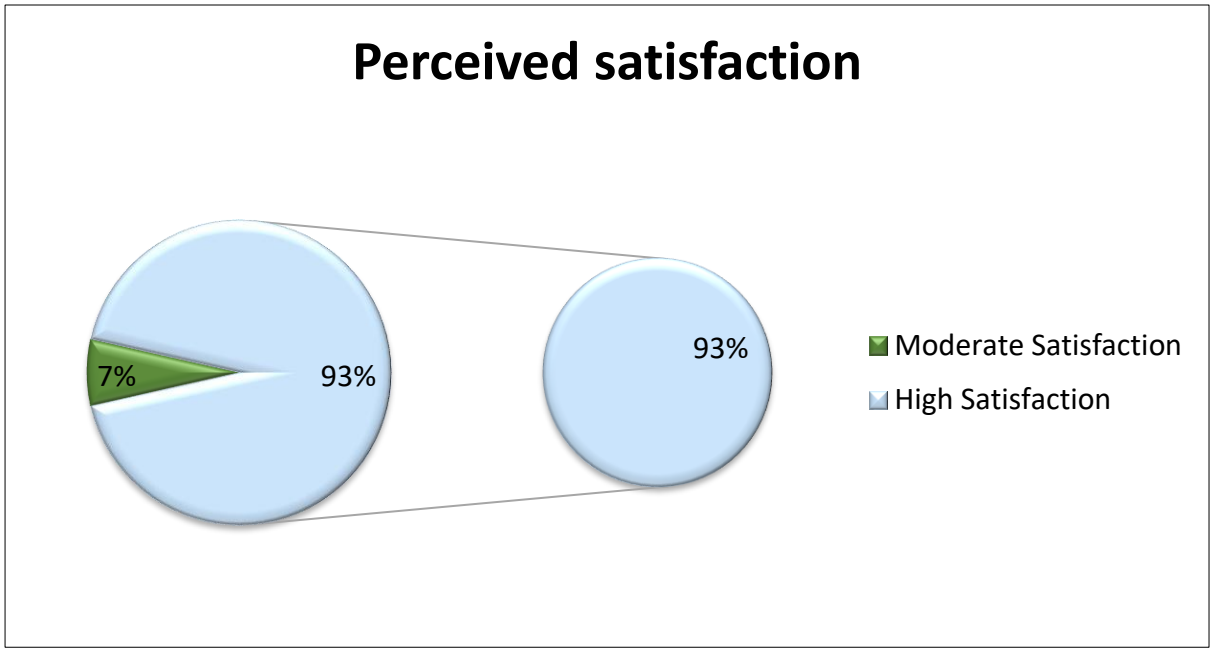

Figure 4.5 : Levels of perceived satisfaction among women with infertility after the intervention.

The present study shows that 89 (93%) women were highly satisfied with the intervention.7 (7%) women were satisfied with the intervention.

CHAPTER - V

RESULTS AND DISCUSSION

5.1 Objective 1:

The present study shows that the significant risk factors identified are **Marital conflicts** Odd ratio 25.159, 95% CI Upper 275.318 Lower - 25.159 ,pvalue0.008*and **a lack of spousal care** Odd ratio 30.499, 95% CI Upper 308.005 Lower - 3.02 ,p value 0.004*****, both of which show strong odds ratios and p-values less than 0.05. Other factors, Dysmenorrhoea, Age at marriage, Type of marriage, Conflict laws, Income sufficient, Frequency of meals, Food habits, coitus, and Hormonal Imbalance show some association, but they are not statistically significant.

The present study findings are supported by a similar study was conducted at the University Institute of Public Health collecting data from Gilani Ultrasound Center by Wafa Fatima a total of 690 women were selected. The women chosen for the case group had to be 20–45 years of age, had any parity, and had a confirmed diagnosis of infertility.[10]

Multiple logistic regression (MLR) and ANN were used. The chance of infertility was 2.91 times higher in women living in a joint family [odds ratio (OR) = 2.91; 95% confidence interval (CI) (1.91, 4.44)] and was also 2.35 times higher for those women who had relationship difficulties with their husband [OR = 2.35; 95% CI (1.18, 4.70)]. Marriage at an earlier age was associated with secondary infertility with β being negative and OR being < 1 [OR = 0.94; 95% CI (0.88, 0.99)]. Hence, identified infertility risk factors are mostly modifiable and can be prevented or treated. By managing these risk factors, we can reduce the risk of infertility.[10]

5.2 Objective 2:

The present study shows that the mean difference in pre-test scores, in the quality of life about Emotional aspect was 0.55, (t=-3.54p <0.002), Relational 0.42,(t=-2.464,p<0.015), Treatment environment 0.2,(t=1.488p<0.139), Treatment tolerability 0.13(t=-0.903,p<0.368). Mind &Body 0.87,(t=-3.015, p<0.003)*,and Social 0.92,(t=5.743,p<0.001*).

A similar cross-sectional study was conducted by Artur Wdowiak, and Agnieszka Anusiewicz, with Abbreviated, this study aimed to assess the quality of life (QoL) of infertility. The study result shows that there is a significantly differed between the study groups and the control (physical domain $p < 0.001$, psychological $p < 0.009$; social $p < 0.004$; environmental $p < 0.001$). A significant effect was found in 4 FertiQoL subscales. The quality

of life depends on reproductive problems, methods of infertility treatment, age, place of residence, and education level.[11]

5.3 Objective 3:

The present study proved that there was a statistically significant improvement in all aspects of quality of life after the intervention at p< 0.001, in all the aspects, with the mean difference in Emotional 5.34, (t==58.840,p<0.001*), Mind & Body:17.53, (t=51.474,p<0.001*), Relational:17.73, (t=81.558,p<0.001*), and Social:10.1, (t=46.919,p<0.001), Treatment environment:10.67, (t=55.136,p<0.001*), Treatment tolerability:8.93, (t=46.201,p<0.025*).

The total mean score of the Study group after the intervention was 123.69 higher than the pre-test score so the quality of life improved after the intervention. Therefore the hypothesis1.H_1 - There is a significant difference in the quality of life of the women with primary infertility in the Study group before and after the intervention is supported.

This clinical trial was conducted on 60 couples (30 couples in the intervention and 30 in the control group) referred to the Infertility Center in Kerman City, Iran, Mokhtari Sorkhani T, Ahmadi A, et.al This study aimed to investigate the effectiveness of integrated psychological counseling with a couple of therapy approach on the quality of life of infertile women. Results showed significant differences between the Mean±SD of the mind-body (88.5±6.39)social (78± 6.34) and emotional (73.75 ±6.71) Results showed a significantly higher FertiQoL total score for the intervention group (70.56±6.49) compared to the control group (57.76±12.26) at the post-test (P=0.001). The study concludes that integrated psychological counseling could improve the quality of life among infertile women.[12]

A randomized trial study was conducted by Seyed Teymur Seyedi Asl in 2016, Effect of Group Positive Psychotherapy on Improvement of Life Satisfaction and The Quality of Life in Infertile Woman. This study aims to investigate the effectiveness of group-positive psychotherapy on the elevation of life satisfaction and quality of life in infertile women. The results showed that the life satisfaction scores of the intervention group were significantly elevated from 22.66 in the pre-test to 26.13 in the post-test (P<0.001).The difference between the life satisfaction scores of the intervention and the control groups was also significant (F=8.92, P=0.006). Study Concludes that the treatment method could be introduced as a solution to increase life satisfaction in infertile women, but not as a treatment for elevating their quality of life.[13]

5.4 Objective 4:

The present study shows that there is no association between the quality of life among women with primary infertility in the Study group & control groups with selected socio-demographic variables like Age, gender, religion, educational status, occupation, Income, the breadwinner of the family, type of family, residence, the reason for infertility and the risk factors include gynecological factors, psychological factors, lifestyle factors, BMI, hormonal imbalance, cause of infertility and previous infertility problem.

Therefore the hypothesis 2. H_2-There is a significant association between the quality of life among women with primary infertility after intervention in the Study group & control group with selected socio-demographic variables is partially supported.

A community-based cross-sectional study was conducted by Ashwini Katole and Ajeet V Saoji, all married women between 15 and 49 years. The majority of the women (39.3%) belonged to the 25–29 years of age group. Sociodemographic factors that had statistically significant association with infertility were age at marriage more than 25 years ($P < 0.05$), nuclear family ($P < 0.05$), higher education level ($P = 0.04$), employed women ($P < 0.05$), high socioeconomic status ($P = 0.01$), and family history of infertility ($P < 0.05$). Physiological factors that had a statistically significant association with infertility were obesity ($P = 0.03$), age at menarche of more than 14 years ($P < 0.05$), and irregular menstruation pattern ($P < 0.05$). Depression ($P = 0.01$) and stress ($P < 0.05$) were the psychological factors significantly associated with infertility. [14]

5.5 Objective 5:

To assess the perceived level of satisfaction among women with primary infertility after the intervention.

The present study shows that 89 (93%) women were highly satisfied with the intervention, and 7 (7%) women were satisfied with it.

The present study findings are supported by a similar study conducted by Mohamed, H.M., Badia, T.S., Khalaf, S.A. *et al.* (2024) study design aimed to evaluate the effect of a health education program on knowledge, stress, and satisfaction among 100 infertile women undergoing IVF attending the Woman's Health Hospital's infertility outpatient clinic and IVF unit at Assiut University. Knowledge and stress were measured by women's knowledge about IVF and the perceived stress scale, respectively. The satisfaction was measured using the Patient Satisfaction Scale for IVF. There is a marked improvement in the knowledge of infertile women, with a significant reduction in their stress levels after the health education program. Furthermore, the satisfaction scores of the women who participated in the program improved significantly.

CHAPTER - VI

SUMMARY, CONCLUSION, RECOMMENDATIONS AND LIMITATIONS

6.1 SUMMARY

Based on this study these risk factors and providing appropriate support can have a significant positive impact on the well-being of women struggling with infertility. By recognizing and addressing risk factors such as gynaecological factors, lifestyle factors, psychological factors stress, anxiety, and emotional distress, interventions can help to improve mental health, emotional resilience, and overall quality of life for infertile women.

Supportive interventions like Aerobic exercise, Heartfulness relaxation & Meditation for women with primary infertility play a crucial role in providing emotional support, coping strategies, and resources to navigate the challenges of infertility, ultimately leading to improved quality-of-life outcomes. Continued research and implementation of tailored interventions are essential in further enhancing the well-being of infertile women and addressing the complex factors associated with infertility.

6.2 CONCLUSION

- The study concluded that irregular menstrual cycle, job & Social stress, overweight, more of non vegetarian foods, lack of exercise, Hormonal imbalance were some common risk factors associated with infertility.
- The heartfulness relaxation and meditation and Aerobic exercise like walking and jogging significantly improved their quality of life in the experimental group in all aspects.
- The tool was found feasible and practicable.

6.3 STRENGTHS OF THE STUDY

- Randomised Controlled Trial, Registered under CTRI
- Study and control groups were selected randomly avoiding the contamination of interventional information between the groups.
- A well planned intervention for 4 Weeks based on the Calista Roy adaptation Model
- A planned and organised follow up by the researcher

6.4 LIMITATIONS OF THE STUDY

The study findings

1. Are based on the self-reports of the participants.
2. The intervention practiced by the participant was not directly observed by the researcher.

3. It could be generalized to a limited population only
4. The fact that it is a Randomized block design

6.5 RECOMMENDATIONS OF THE STUDY

Institutions

- ❖ Comparative study to identify male and female infertility factors.
- ❖ A study to analyse the social stigma undergone by women with impaired fertility.
- ❖ An interventional study to identify the effectiveness of meditation in reducing stress among infertile couples.
- ❖ An interventional study on weight reduction and its effectiveness in promoting fertility.

Individual/Independent Nurses

- Qualified Nurses can adopt the study and start the individual nurse led centres for women's health in the urban and rural areas.

6.6 IMPLICATIONS OF THE STUDY

NURSING ADMINISTRATION

Nursing administrators should see that enough support is provided in terms of manpower, money, and material for disseminating health information regarding infertility. The study findings have shown clearly the responsibility of nurse administrators in organizing in-service education and counselling session for patients with infertility.

NURSING EDUCATION

1. Nurse educators can teach about the factors contributing to infertility in classrooms so that students become more aware of them.
2. Nurses can be involved in organizing workshops Prevention of infertility and its management
3. Involvement of students in a training program to create awareness of infertility and its cause.

NURSING PRACTICE

1. Midwives can conduct regular Health education programs on the modification ways of those identified factors that will promote fertility.
2. Advice them to do regular exercise to improve blood circulation, and demonstrate yoga and Meditation to calm the mind, as well the mind to relieve stress.

NURSING RESEARCH

- This study can be done at various dimensions like the comparison between rural and urban, hospitals and health canters, future investigators can use the findings and methodology as references.
- More research is needed to address the benefits of exercise and meditation. Healthcare providers need more scientific information to be better able to collaborate with women regarding treatment choices. More longitudinal studies would be helpful to determine the best learning programs for women, as well as measure health status over time.

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ANNEXURES

SRI BALAJI VIDYAPEETH
Examinations

OFFICE OF THE CONTROLLER OF EXAMINATIONS
Dr. **S. SRIRANGARAJ**
Controller of Examinations

Date: 21-06-2023

No. SBV/COE/Ph.D/A5

UNIVERSITY MEMORANDUM

Sub : Sri Balaji Vidyapeeth – Ph.D Degree in Part – I Course Work Assessment – Results Notified.

* * * * *

Mr/Mrs/Dr. **PON PRINCESS MANO,** UIN. **2005002006** Research Scholar in Nursing (Part Time - External) is declared to have passed the Ph.D Part-I – Course Work Assessment and he/she is permitted to continue the research under the guidance of Dr. **SUJATHA T** and submit the thesis for the award of Ph.D Degree as per the regulations of SBV.

Sl. No.	Subjects	Result Status
1	PAPER - I RESEARCH METHODOLOGY AND BIOSTATISTICS	**PASS**
2	PAPER - II ON CHOSEN FIELD OF RESEARCH	**PASS**

SRI BALAJI VIDYAPEETH CONTROLLER OF EXAMINATIONS PONDICHERRY

S. Sriranjaraj

CONTROLLER OF EXAMINATIONS

To : Mr/Mrs/Dr. **PON PRINCESS MANO**

CC : Dr. **SUJATHA T**, Prof. & Head of Community Health Nursing, SSSCON.

SRI BALAJI VIDYAPEETH

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CERTIFICATE

This is to Certify that Dr./Mr./Ms..... Pon Princess Mano .....

UIN No..... 2005002006 .....*Department of* Obstetrics and gynecological Nursing .....

has attended, actively participated and fulfilled the requirements as per University norms of the online workshop on ***"RESEARCH METHODOLOGY, BIO-STATISTICS AND PREPARATION OF SCIENTIFIC MANUSCRIPT"*** *conducted by Sri Balaji Vidyapeeth, Puducherry from 18.05.2022 to 24.06.2022*

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(Regd. With CDSCO- Reg. No.ECR/400/Inst/Py/2013-RR20
& DHR-Reg.No.EC/NEW/INST/2021/PY/0015)
Decision of the IEC

Date: 08.02.2022 **Faculty Proposal** **REF NO:** **IEC: RC/2021/76**

Protocol Title	Identification of Risk factors Associated with Infertility and the Effect of Supportive Intervention on Quality of Life among women with primary infertility in selected hospitals Puducherry – A Randomized Control Trial
Name of the Principal investigator	Mrs. Pon Princess Mano
Name of the Co-investigators	-
Name of the Department & Institution	Department of Obstetrics & Gynecology Nursing / Pondicherry Institute of Medical Sciences
New Review / Old Review	New Review
Date of Review (DD/MM/YYYY)	11.01.2022
Decision of the IEC (Approved / Approved with suggested modifications / Pending / Revision / Rejected)	Approved from 11.01.2022 for a period of 36 months until 10.01.2025
Remarks	Nil

Please note*

- Inform IEC immediately in case of any adverse events and serious adverse event.
- Inform IEC in case of any amendments to the protocol, change of study procedure, site and investigator and premature termination of study with reasons along with summary.
- Final & yearly reports to be submitted to IEC.
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09/02/22

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11.02.2025

TO WHOM SO EVER IT MAY CONCERN

DATA COLLECTION COMPLETION CERTIFICATE

Mrs. Pon Princess Mano, UIN 2005002006 pursuing PhD Nursing (Obstetrics and gynaecology) at Sri Balaji Vidyapeeth University, Puducherry, completed her data collection from January 2023 to December 2023, for research entitled " Identification of Risk factors Associated with Infertility and the Effect of Supportive Intervention on Quality of Life among women with primary infertility in selected hospitals Puducherry" – A Randomized Control Trial.

Dr. Mary Daniel

Professor & HOD

Deparment of Obstetrics & Gynecology Nursing

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PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

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THE SCIENTIFIC SOCIETY

Acknowledges that

MRS. PRINCESS MANO

has presented the Poster/Paper titled

IDENDIFICATION OF RISK FACTORS ASSOCIATED WITH INFERTILITY AND THE EFFECT OF SUPPORTIVE INTERVENTION ON QUALITY OF LIFE AMONG WOMEN WITH PRIMARY INFERTILITY A RANDOMIZED CONTROL TRIAL

on **"THE SCIENTIFIC SOCIETY DAY"** *held on the*

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Advances in Bioresearch

REVIEW ARTICLE

Defining Infertility—A Systematic Review of Effect of Intervention on Quality of Life of Infertile Women

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ABSTRACT
Fertility plays a vital role in a woman's life.[1]Infertility affects 8%–12% of the couples of reproductive ages, and about 15% of the couples would experience subfertility during the 1st year after their marriage, while the total prevalence of fertility in Iran has been reported as 8% and 13.2%.[4] Experiencing infertility is associated with a wide range of psychological problems such as stress, anxiety, depression, feeling humiliated, low self-esteem, feeling of inefficiency, and lower psychological adaptation. A systematic literature search was conducted from Jan 2015 to December 2021.Published thesis and articles from various national and international database such as pubMed, Scopus, Proquest, Medline were included in the review up to 2021.The keyword used to search the literature were infertility, counseling, supportive intervention, Meditation, Relaxation. Fertiqol and Google search engine was also used to explore the open access publications. A total of 2602 citations were evaluated, with 185 full-text papers being examined. A total of 15 articles were included in the current review. The results highlight that interventions aiming at improving FertiQoL in infertile women, Therapeutic gains were maintained regarding depression and anxiety symptoms, independently of the reproductive outcome, spousal support program was well-received and significantly improved part of the QoL and women experiencing infertility difficulties should direct their attention to social roles other than motherhood. As interventions like counselling and psychological interventions, educational programmes increase quality of life among infertile women, those are highly recommended for the management of infertile couples.
Key words: infertility, definition, epidemiology, Infertile Women

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INTRODUCTION

Fertility plays a vital role in a woman's life. In our tradition fertility is the most important part of marital life. The feeling of being conceived is wonderful, and the mother is bound with joy on the first kick of her child inutero [2].

Infertility is defined as a failure to conceive within one or more years of regular unprotected coitus. Primary infertility denotes those patients who have never conceived. Secondary infertility indicates previous pregnancy but failure to conceive subsequently [1]. Fecundability is defined as the probability of achieving a pregnancy within one menstrual cycle. The male is directly responsible in about 30–40

percent, the female in about 40–55 percent and both are responsible in about 10 percent cases. The remaining 10 percent is unexplained [5].

The important causes of male infertility are, Hypothalamic-pituitary disorders (1–2%). (2) Primary gonadal disorders (30–40%), Disorders of sperm transport (10–20%) and (4) Idiopathic (40–50%). Congenital – Undescended testes, Kartagener syndrome (autosomal disease)Hypospadias , varicocele. Infection, malnutrition or heavy smoking[3].

Causes of female infertility According to FIGO manual (1990) causes are,Tubal and peritoneal factors (25–35%), Ovulatory factor (30–40%) and Endometriosis (1–10%). Drug induced ovulation, decreased level of FSH and/or LH, elevated prolactin, subclinical hypothyroidism, older women, pelvic endometriosis, dysfunctional uterine bleeding are the important causes. Vaginitis and purulent discharge may at times be implicated but pregnancy too often occurs in presence of vaginitis, specific, or nonspecific. However, dyspareunia may be the real problem in such cases [6].

Infertility affects 8%–12% of the couples of reproductive ages, and about 15% of the couples would experience subfertility during the 1st year after their marriage, while the total prevalence of fertility in Iran has been reported as 8% and 13.2%. Experiencing infertility is associated with a wide range of psychological problems such as stress, anxiety, depression, feeling humiliated, low self-esteem, feeling of inefficiency, and lower psychological adaptation. Hence, the necessity of psychological treatments for infertile women should be attended more. Infertility would affect women's sense of well-being in both psychological and social domains. In some societies, infertility is considered as women's responsibility and infertile women would experience a feeling of guilt, negative imagination, and lowered self-esteem. Infertility also affects sexual behaviours and these women would experience a high rate of nonphysical domestic violence. In fact, infertility and its treatment process is a mentally suffering source for infertile women that have destructive effects on their mental well-being, infertile women have lower psychological well-being and higher psychological frustration compared to infertile men. Hence, using strategies for psychological empowerment of infertile women to cope with these consequences is necessary [4, 13-16].

MATERIAL AND METHODS

The review was framed by doing the best effort of searching in an ancient text, available literature, online search, etc. The related literature with supportive intervention like counselling, exercise, relaxation and meditation to improve the quality of women with infertility searched on online platform pubMed, Scopus, Proquest, Medline etc. The published article studied and then planned to analyse. The keyword used to search the literature were infertility, counselling, supportive intervention, Meditation, Relaxation.No other exclusion criteria were applied regarding journals, years, authors, etc. The list prepared is of all articles published until October 2021. The traced article obtained from searching the databases were compiled and screened. The title, abstract and article conclusion was studied. The research study that satisfied the inclusion criteria and that is describing Quality of life among infertile couple were only included, others excluded.

Inclusion Criteria:

- Article published in peer review journals
- Open access thesis available on database
- Article and thesis published from Jan 2015 to December 2021
- Experimental studies
- Quantitative Studies

Exclusion Criteria:

- Review article
- Non Experimental studies
- Qualitative Studies

DATA EXTRACTION

Two reviewers independently extracted data from eligible studies onto a customized data extraction form and populated it with variables about the study population and phenomena of interest. The third review author double-checked and verified extracted articles. Study characteristics that were extracted included the name of the first author and year of publication, data collection period and region in which the study was conducted. In addition, specific study details were captured, including the study design, population, sample size, sampling procedures and data collection procedures. Effect of intervention on quality of life among infertile was systematically identified.

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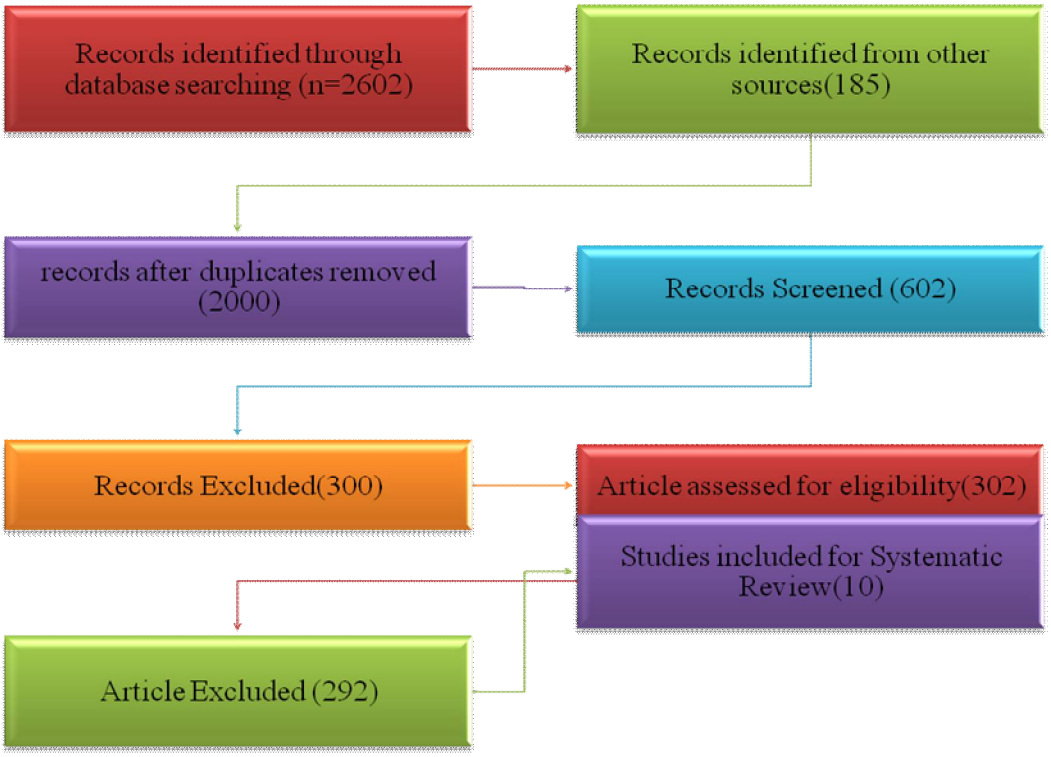
RESULT

All selected matters from articles or books were grouped and screened properly. The text and abstract were read thoroughly and analysed. The "PRISMA" (the preferred reporting items for systematic review and meta-analysis) guidelines [14] was adopted to describe this systematic review . Supportive intervention like counselling, exercise, relaxation and meditation helps to improve the quality of women with infertility.

DISCUSSION

Mindfulness-based interventions aiming at improving FertiQoL in infertile women. Therapeutic gains were maintained regarding depression and anxiety symptoms, independently of the reproductive outcome. The spousal support program was well-received and significantly improved part of the QoL improved knowledge on the impact on the fertility window , understanding of information significantly improved knowledge of key reproductive health concepts.

Systematic Review of supportive intervention on infertility


Records identified through database searching (n=2602)
Records identified from other sources(185)
records after duplicates removed (2000)
Records Screened (602)
Records Excluded(300)
Article assessed for eligibility(302)
Studies included for Systematic Review(10)
Article Excluded (292)

SL.NO	AUTHOR	Type of study	FINDINGS
1	Galhardo, *et al* [7]	A 7-year follow up study on long term effects of mindfulness-Based Program for Infertility. Fifty-five women attended the MBPI sessions and completed self-report measures of depression, anxiety, mindfulness, and experiential avoidance at post-MBPI (T1), 6-month follow-up (T2), and 7-year follow-up (T3).	There were long-term effects of MBPI on mindfulness and experiential avoidance. Therapeutic gains were maintained regarding depression and anxiety symptoms, independently of the reproductive outcome.
2	Asazawa, K., et.al [8]	quasi-experimental study on Effectiveness of a spousal support program in improving the quality of life of male patients undergoing infertility treatment: A pilot study among 30 infertile couple	There were significant differences in relational and emotional sub-scales of QoL. Majority of the participants expressed satisfaction with the program. The spousal support program was well-received and significantly improved part of the QoL

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3	Hosseini, M.S., et.al [9]	Randomized controlled clinical trial on Effects of a short-term mindfulness-based stress reduction program on the quality of life. 36 women with infertility, who were selected by consecutive sampling. Women either participated in the MBSR program or received routine consultation in eight two-hour group sessions once a week. Women's QoL was measured using the 36-item short-form health survey before, immediately after, and one month after the intervention.	Short-term MBSR program seem to be potentially effective in improving the QoL of women with infertility.
4	Luk, B. H., & Loke, A. Y. [10]	Systematic review of 23 articles on supportive interventions targeting individuals or couples undergoing infertility treatment: Directions for the development of interventions	Cognitive behavioral therapy (CBT), acceptance and commitment therapy (ACT), and counseling were the most commonly adopted psychosocial interventions for infertile individuals or couples.
5	Clifton, J.[11]	A randomized pilot trial on effect of An internet-based mind/body intervention to mitigate anxiety in women experiencing infertility. Seventy-one women were randomly assigned to the intervention or a wait-list control.	At mid-assessment, relative to the waitlist group, the intervention group had a lower level of depressive symptoms and, for those with elevated anxiety symptoms at baseline, a lower level of anxiety symptoms. The findings suggest that even a partially completed internet-based intervention can reduce the anxiety and depressive symptoms of women with a diagnosis of infertility.
6	Meacham, L. R., Williamson-Lewis, R., et.al [12]	Two-phase prospective study on effect of Educational intervention to address infertility-related knowledge gaps among adolescent and young adult survivors of childhood cancer. Sessions used sex-specific visual aids (phase I) or a personalized handout (phase II). Surveys assessing knowledge of overall risk for infertility (yes/no), level of risk (none, low, moderate, or high), relative impact of treatment on the window of fertility (same/less than peers), and the need to use protection to prevent pregnancy (yes/no) were completed at baseline and 1-month follow-up.	The educational intervention improved knowledge on the impact on the fertility window, understanding of information significantly improved knowledge of key reproductive health concepts.
7	van Elten, T. M., Karsten, M. D. A., et.al [13]	Multicentre randomised controlled trial (RCT) on Preconception lifestyle intervention reduces long term energy intake in women with obesity and infertility: A randomised controlled trial. 577 women with obesity and infertility aged 18 to 39	A preconception lifestyle intervention led to reduced energy intake 5.5 years later. Additionally, women allocated to the intervention group who were successful in losing weight during the intervention also had a lower BMI at follow-up. This shows the potential sustainable effect of a preconception lifestyle intervention.
8	Aiyenigba, A. O [14]	Quantitative research on Interventions to reduce psychological morbidities associated with infertility in Nigeria. 224 patients attending infertility clinics in 2 Nigerian cities	findings suggest that intervention to be empowering and beneficial in helping them manage infertility induced psychological distress.

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9	Kim, M., Moon, S., & Kim, J[15]	Effects of psychological intervention for Korean infertile women under in vitro fertilization on infertility stress, depression, intimacy, sexual satisfaction and fatigue	psychological intervention cantered on the marital and personal dimensions may improve marital intimacy and sexual satisfaction.
10	van Dammen, L., Wekker, V., et.al [16]	randomized controlled trial on the effects of a pre-conception lifestyle intervention in women with obesity and infertility on perceived stress, mood symptoms, sleep and quality of life	Five years after randomization, no differences were observed for perceived stress, mood symptoms, sleep quality and QoL between the intervention (n = 84) and control groups (n= 94).There was selective participation: women who did not participate in the follow-up had lower baseline mental QoL, and benefitted more from the intervention in terms of improved physical QoL during the original LIFEstyle intervention. Conclusions: We found no evidence that a pre-conception lifestyle intervention improved female wellbeing five years after randomization.

CONCLUSION

A review on interventions reveals that counseling interventions and perceived social support greatly influence the physical and mental condition, life satisfaction, and various aspects of infertile women's life quality, and they have been recognized as moderating factors effective in dealing with stress and coping with stressful conditions. Considering the fact that there is an international agreement that fertility centers need to offer counselling programs for psychological problems of the infertile, it is especially important to recognize counselling-supportive interventions for decreasing infertile women's perceived stress, and to program plans for decreasing women's perceived stress. By investigating counselling-supportive stress, we hope that this study has stepped forward toward health care agent's familiarity with decreasing infertile women's perceived stress and, therefore, improving treatment consequences.

Strengths and limitations of the systematic review

The included studies had relatively small sample sizes, resulting in low power to our results. We could not conduct analyses to explore potential bias associated with the heterogeneity between studies because of the small number of included studies. Most of the included studies used cross-sectional, which reduces our confidence in these results because bias can be introduced.

CONFLICT OF INTEREST

Conflict of interest declared none.

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RESEARCH ARTICLE

Identify the Risk Factors Associated with Infertility among Women with Primary Infertility in Selected Hospitals in Puducherry

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ABSTRACT

According to the Gynaecological factors most of them belonged to the age group of 13 – 15 years, The Days of menstrual flow was 3 – 5 days, Premenstrual symptoms were Rarely present, Most of them were Non-Consanguineous 25(83.3%),Patterns of occurrence of menstrual cycle Once in 33 – 45 days 15 (50%) were 15(50%)were Once in 28 days, Years of Marital life most of them in the age group of4 - -6 years 13 (43.4%). Most of them were there is no family history of inherited conditions 23(76.7%), and 7(23.3%) hada family history of DM. According to the Psychosocial factors17 (73.3%)women have marital conflicts, Most of them16 (53.3%) have Conflicts with In-Laws, 14 (46,7%) were there are Conflicts with In-Laws, Income sufficient to run their family13 (43.3%)& 17(56.6%)there is no sufficient Income to run the family,20(66.7%) Spouse were caring towards their wives where else 10 (33.3%)Spouse was not caring towards their wives,Most of them 25(83.3%).

Keywords: Due to population growth, however, the absolute number of couples affected by infertility increased from 42.0 million (39.6 million, 44.8 million) in 1990 to 48.5 million (45.0 million, 52.6 million) in 2010[2].

INTRODUCTION

Infertility is a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after the 12th month or more of regular unprotected sexual intercourse. Infertility is a global health issue affecting millions of people of reproductive age worldwide. Available data suggests that between 48 million couples and 186 million individuals have infertility globally. Infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse. Due to population growth, however, the absolute number of couples affected by infertility increased from 42.0 million (39.6 million, 44.8 million) in 1990 to 48.5 million (45.0 million, 52.6 million) in 2010[2].

OBJECTIVES

1. To Asses the Demographic Variables among the women with primary infertility
2. To identify the risk factors associated with infertility among women with primary infertility.

METHODOLOGY

RESEARCH APPROACH: Quantitative approach
RESEARCH DESIGN: Descriptive research design
RESEARCH VARIABLES:
INDEPENDENT VARIABLE: Gynecological factors, Psychological factors, and Lifestyle factors.

DEMOGRAPHIC VARIABLES

It includes socio-demographic variables like age, religion, occupation, type of family, marital status, family income, occupation, Source of income, and Residence. Years of married life

RESEARCH SETTING

The study will be conducted on the women attending infertility clinics at selected tertiary hospitals in Pducherry.

TARGET POPULATION

The population of the present study comprises all Women with primary infertility

SAMPLING TECHNIQUE: Convenience sampling Technique

SAMPLE SIZE: 30

SAMPLING CRITERIA

INCLUSION CRITERIA

- Women in the age group of 23 - 45 years with primary infertility
- Women who are willing to participate

EXCLUSION CRITERIA:

- Women who arenot willing to participate

MATERIAL AND METHODS OF DATA COLLECTION

1. A prior Formal administrative permission was obtained from the Director- Principal, IRB, Ethical committee,

HOD OBG Department, and concerned authorities at the time of data collection.

2. Informed consent was obtained from the participants after explaining the nature and purpose of the study.
3. The Study Participant's details were confidential throughout the study period.
4. A Convenience sampling method was selected based on the inclusion criteria. Informed consent was taken from the participants before collecting data.
5. A total of 30 samples were used for this study. An assessment was done to Identify risk factors associated with infertility by using a structured interview Questionnaire. The data was analyzed in descriptive statistics by the objectives.

ORGANIZATION OF THE RESULTS

The findings of the analysis are presented in the following sections

Section 1: Description of socio-demographic variables

Section 1I: To Describe The Level Of The Risk Factors Associated With Infertility Among Women With Primary Infertility.

FINDINGS AND RESULTS

SECTION A: DISTRIBUTION OF PARTICIPANTS ACCORDING TOSOCIO-DEMOGRAPHIC VARIABLES

Table 1 Above shows the women's frequency and percentage distribution about their sociodemographic characteristics. The majority of the women 17(56.6%)belonged to the age group of 21 to 30 years, all were Hindu, 7(46.7) had only completed their secondary educationin both groups, Majority of the women were housewives15(50%) and according to the income most of their family income was Rs.10,001 – 30000.20(66.6%).The Breadwinner of the family is the husband 23 (76.6%)In terms of family type, The majority of women have Nuclearfamilies25(83.3%)withthe residence majority 18(60%) belonging to urban areas. The majority of the women have infertility problems25(83.3%) due to female factors.

SECTION 1I: **TO DESCRIBE THE LEVEL OF THE RISK FACTORS ASSOCIATED WITH INFERTILITY AMONG THE WOMEN WITH PRIMARY INFERTILITY IN EXPERIMENTAL & CONTROL GROUP.**

Table 2: Abovetable shows that most of them belong to the age group of 13 – 15 years, The Days of menstrual flow were 3 – 5 days, Premenstrual symptoms are Rarely present, Most of them were Non-Consanguineous 25(83.3%),Pattern of occurrence of menstrual cycle Once in 33 – 45 days 15 (50%)were 15(50%)were Once in 28 days, Years of Marital life most of them in the age group of4 - -6 years13 (43.4%).Most of them were there is no family history of inherited conditions 23(76.7%), and 7(23.3%)hada family history of DM. **Table**:3 According to the Psychosocial factors17 (73.3%)women have marital conflicts, Most 16(53.3%) Conflicts with In-Laws,14 (46,7%) where there are Conflicts with In-Laws, Income is sufficient to run their family13(43.3%)&17(56.6%)there is no sufficient Income to run the family,20(66.7%) Spouse were caring towards their wives where else 10 (33.3%)Spouse was not caring towards their wives,Most of them 25(83.3%) women are having job social stress.&5(16.7%) there is no job social stress. **Table** In lifestyle factors most of them were nonvegetarian23(76.7%)Frequency of meals regularly 3 meals 30(100).According to the type of exercise most of them 19(63.3%)only Household work, There were no personal habits,14(46.7%) women were exposed to passive smoking16 (53.3%)were note exposed to passive smoking, among them11(36.7%) having coitus Once a week in, all of them were not using any contraceptive methods.

The finding of the Study

According to the Gynaecological factors most of them belonged to the age group of 13 – 15 years, The Days of menstrual flow was 3 – 5 days, Premenstrual symptoms were Rarely present, Most of them were Non-Consanguineous 25(83.3%),Patterns of occurrence of menstrual cycle Once in 33 – 45 days 15 (50%) were 15(50%)were Once in 28 days, Years of Marital life most of them in the age group of4 - -6 years 13 (43.4%). Most of them were there is no family history of inherited conditions 23(76.7%), and 7(23.3%) hada family history of DM. According to the Psychosocial factors17 (73.3%)women have marital conflicts, Most of them16 (53.3%) have Conflicts with In-Laws, 14

(46,7%) were there are Conflicts with In-Laws, Income sufficient to run their family13 (43.3%)& 17(56.6%)there is no sufficient Income to run the family,20(66.7%) Spouse were caring towards their wives where else 10 (33.3%)Spouse was not caring towards their wives,Most of them 25(83.3%) women have job social stress.& 5(16.7%) there is no job social stress. In lifestyle factors, most of them were nonvegetarian23(76.7%)Frequency of meals regularly 3 meals 30(100).According to the type of exercise most of them 19(63.3%)only Household work, There were no personal habits,14(46.7%) women were exposed to passive smoking16 (53.3%)were not exposed to passive smoking, among them 11(36.7%) having coitus Once a week in, all of them were not using any contraceptive methods.

CONCLUSION

This study identified certain modifiable factors contributing to infertility. The study concluded that irregular menstrual cycles, marital and familial conflicts, more non vegetarian foods, lack of exercise, etc were some common risk factors associated with infertility. The study concluded with certain awareness of the modifiable factors and ways to modify them will always contribute towards the betterment of women's health in terms of fertility. There are so many measures to diagnose infertility after its onset, but prevention is always better than cure. Likewise, by identifying the preventive and modifiable factors, infertility can be reduced in its occurrence. Also, this study takes its part in contributing, to the achievements of Infertility reduction aspects.

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Table 1: Frequency and percentage distribution of women with Primary infertility according to socio-demographic variables n=30

SL.NO	DEMOGRAPHIC VARIABLES		
		n	%
1	**AGE (in years)**		
	21-30 yrs	17	56.6
	> 30 yrs	13	43.3
2	**Religion**		
	a. Hindu	30	100
3	**Educational status**		
	Primary	7	23.3
	Secondary	14	46.6
	Graduate	9	30
4	**Occupation**		
	Housewife	15	50
	Employee	11	36.6

PART I: Distribution of participants according to thegynecological factors associated with primary infertility. n=30

SL.NO	Menstrual and Marital history	n	%
1	**Age of menarche**		
	a. 13 – 15 years	30	100
2	**The pattern of occurrence of the menstrual cycle**		
	a. Once in 28 days	15	50
	b. Once in 33 – 45 days	15	50
3	**Days of menstrual flow**		
	a. 3 – 5 days	30	100
4	**Premenstrual symptoms**		
	a. Rarely present	30	100
	a. Dysmenorrhoea, abdominal cramps		
	a. Rarely present	30	100
5	**Age at marriage**		
	a. 21 – 25years	26	86.7
	b. 26 – 30years	4	13.3
6	**Type of marriage**		
	a. Consanguineous	5	16.7

	b. Non Consanguineous	25	83.3
7	**Years of Marital Life**		
	a. 1 – 3years	4	13.3
	b. 4 - -6 years	13	43.4
	c. 7– 9 years	7	23.3
	d. > 12 years	6	20
8	**Inherited conditions**		
	a. Yes (DM)	7	23.3
	b. No	23	76.7

PART 2:Distribution of participants according to the Psychosocial Factors Associated With primary Infertility. n=30

SL.NO		f	%
1	**Marital conflicts**		
	a. Yes	17	73.3
	b. No	13	26.7
2	**Conflicts with In-Laws**		
	a. Yes	16	53.3
	b. No	14	46.7
3	**Income sufficient to run the family**		
	a. sufficient	13	43.3
	b. Not Sufficient	17	56.6
4	**Caring exhibited by a spouse**		
	a. Yes	20	66.7
	b. No	10	33.3
5	**Any job stress /social stress**		
	a. Yes	25	83.3
	b. No	5	16.7

PART 3:Distribution of Participants according to the Life Style Factors Associated With Primary Infertility Among Experimental & Control Groups. n=30

SL.NO	Life Style Factors	f	%
1	**Type of food**		
	a. Vegetarian	7	23.3
	b. Non Vegetarian	23	76.7
2	**Frequency of meals**		
	a. Regularly 3 meals	30	100
3	**Food habits**		
	a. More of vegetarian	7	23.3

	b. More of nonvegetarian	23	76.7
4	**Type of exercise do you practice**		
	a. Household works	19	63.3
	b. Walking	11	36.7
5	**Any Personal habits**		
	a.None	30	100
6	**Exposure to passive smoking**		
	a. Yes	14	46.7
	b. No	16	53.3
7	**Frequency of coitus**		
	a. Once a week	11	36.7
	b. Twice a week	7	23.3
	c. More than twice a week	7	23.3
	d. Occasionally	5	16.7
8	**Usage of Contraceptive**		
	a. Natural Method	30	100

RESEARCH
O&G Forum 2024; 34 – 2s: 60 - 63

QUALITY OF LIFE OF WOMEN WITH PRIMARY INFERTILITY -A PILOT STUDY

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Abstract
Introduction and Background:
Infertility, a prevalent global health concern, impacts millions worldwide, with estimates ranging from 48 million couples to 186 million individuals affected. Beyond physical assistance, women facing infertility necessitate mental and emotional support to enhance both fertility prospects and overall well-being. This holistic approach aims to uplift mental health and elevate the quality of life for those grappling with infertility.
Methods: This randomized control trial was conducted among women with primary infertility aged between 21 and 45 years attending OPD at selected tertiary hospitals in Puducherry. The study aims to assess the quality of life before intervention among women and to determine the effect of intervention on the quality of life among women with primary infertility. Participants were assigned to 4 blocks, a total of 30 Samples, based on the inclusion criteria after obtaining informed consent, participants were randomly assigned to the intervention and control groups within each block. On the first day for the experimental group, the researcher did direct counselling including the Coach method—aerobic exercise like walking, Jogging, Skipping, and cycling daily 30 minutes for 6 consecutive weeks. Data was analysed by Frequency & percentage, t-test. Observation and follow-up were done through WhatsApp or phone calls.
Result:
There was a statistically significant improvement in all aspects of quality of life ie, Emotional 10.326, (t=23.620 p=0.000), Mind & Body MD10.738,t=15.976 p=0.000*, Relational MD 9.776,t=20.917,p=0.000*, Social MD 3.960,t=9.025,p=0.000*,Treatment environment MD 2.776,t=4.404,p=0.001*, Treatment tolerability MD 4.185,t=13.208,p=0.000* after the intervention at p<0.05.

CONCLUSION:
Quality of life was improved after the intervention including Aerobic exercises like walking and jogging to the experimental group of infertile women.
Keyword: Primary Infertility, Quality of life, Aerobic exercises. Intervention.

INTRODUCTION

Pregnancy and childbirth Reproduction is considered a divine bestowment upon all living beings, wherein each human is granted the gift of life upon birth. Each passing day not only offers the opportunity to exist but also to procreate, thereby doubling one's joy. However, infertility, a disorder of the reproductive system, manifests when clinical pregnancy fails to materialize after twelve or more months of consistent, unprotected sexual activity.

According to estimates from the World Health Organization (WHO), the prevalence of primary infertility in India spans from 3.9% to 16.8%. This statistic varies significantly across Indian states, with states like Uttar Pradesh, Himachal Pradesh, and Maharashtra experiencing a prevalence of around 3.7%, while Andhra Pradesh stands at 5%, and Kashmir at 15%. Additionally, within the same regions, prevalence rates fluctuate among different tribes and castes, highlighting the complex interplay of cultural and genetic factors in infertility.

To address this pressing issue, a proposed study seeks to investigate the impact of aerobic exercises, such as walking, jogging, skipping, and cycling, on the quality of life among infertile women. Aerobic exercises, known for their cardiovascular benefits, have garnered attention for their potential to enhance overall well-being, including mental and emotional health. By focusing on physical activity as a potential intervention, this study aims to explore holistic approaches to improving the lives of infertile women[1-4] .

The significance of this study lies in its potential to offer practical solutions for managing infertility-related challenges. Beyond medical treatments, lifestyle modifications, such as engaging in regular aerobic exercises, hold promise in improving both physical health and psychological resilience among individuals grappling with infertility. Moreover, by considering the diverse cultural landscape of India, this research aims to tailor interventions that are sensitive to regional variations in attitudes towards health and wellness.

METHODOLOGY

A research study was conducted focusing on women aged between 21 and 45 years experiencing primary infertility, who were receiving outpatient care at selected tertiary hospitals in Puducherry. Employing a quantitative approach, the study aimed to evaluate the impact of an intervention on the quality of life among women with primary infertility, comparing an experimental group to a control group. Prior to data collection, ethical clearance was obtained from the Institutional Review Board, and formal permission was secured from relevant authorities. Participants meeting the inclusion criteria were grouped into four blocks, with a total of 30 samples, and provided informed consent before enrollment.

Within each block, participants were randomly assigned to either the intervention or control group. Baseline data were collected using questionnaires and the FertiQol standardized tool to assess the quality of life among infertile couples in both groups. For the experimental group, the intervention involved direct counseling sessions, employing the Coach method, which included aerobic exercises such as walking, jogging, skipping, and cycling for 30 minutes daily over a period of six consecutive weeks. Confidentiality of participant information was rigorously maintained throughout the study duration.

Data collected were analyzed using descriptive and inferential statistics to discern any significant differences between the experimental and control groups. Observation and follow-up procedures were conducted using digital communication platforms such as WhatsApp or phone calls to ensure continued engagement and monitor progress among participants.

By adopting this structured approach, the study sought to provide insights into the efficacy of aerobic exercises combined with counseling in enhancing the quality of life for women experiencing primary infertility. The utilization of standardized tools and rigorous ethical protocols aimed to uphold the integrity and reliability of the findings, contributing valuable evidence to inform future interventions and healthcare practices in the field of infertility management

RESULTS

Table 1: The frequency and proportional distribution of women having primary infertility based on socio-demographic characteristics N=15+15=30

SL.NO	DEMOGRAPHIC VARIABLES	Experimental Group		Control Group	
		f	%	f	%
1.	**AGE (in years)**				
	21-30 yrs	10	66.7	7	46.7
	> 30 yrs	5	33.3	8	53.3
2.	**Religion**				
	a. Hindu	15	100	15	100
3.	**Educational status**				
	a. Primary	3	20	4	26.67
	b. Secondary	7	46.7	7	46.7
	c. Graduate	5	33.3	4	26.66
4.	**Occupation**				
	a) Housewife	8	53.3	7	46.67
	b) Employee	6	40	5	33.3
	c) Business	1	6.67	3	20
5.	**Income (per month)**				
	a. Rs.10,001 – 30000	8	53.3	12	80
	b. Rs. 30001 – 50000	7	46.7	3	20
6.	**Breadwinner of the family**				
	a. Husband	12	80	11	73.33
	b. Both	3	20	4	26.67
7.	**Type of family**				
	Joint	3	20	2	13.33
	Nuclear	12	80	13	86.67
8.	**Residence**				
	a) Urban	6	40	6	40
	b) Rural	9	60	9	60
9.	**Reason for infertility**				
	a) Male factor	2	13	3	20
	b) Female factor	13	87	12	80

Table 1 illustrates the demographic characteristics of participants in the experimental and control groups. Among women in the experimental group, 10 (66.7%) were aged between 21 to 30 years, while in the control group, 8 (53.3%) were in the same age bracket (>30 years). All participants in both groups identified as Hindus. In terms of education, 7 (46.7%) women in each group had completed only secondary education. The majority of women, 8 (53.3%) in the experimental group and 7 (46.67%) in the control group, were housewives. Regarding family income, 8 (53.3%) participants in the experimental group and 12 (80%) in the control group reported a family income ranging from Rs. 10,001 to 30,000. Similarly, the husbands were the primary breadwinners for 12 (80%) participants in the experimental group and 11 (73.33%) in the control group. Nuclear families were predominant in both groups. Moreover, the majority of participants, 9 (60%) in the experimental group and an equal number in the control group, hailed from rural areas. Male factor infertility was the primary reason for infertility in most cases, with 13 (87%) participants in the experimental group and 12 (80%) in the control group attributing infertility to this cause.

Table 2: Comparison of Quality of life of Women with primary infertility among the Control Group and Experimental Group after the Intervention.

N=15+15=30

Test	Experimental Group		Control Group	
	f	%	f	%
Pre Test	15	46.6	15	42.5
Post Test	15	83.1	15	43.5

The above table shows that post-test scores of the Quality of life of women in the experimental group are higher (83.1%) than women in the control group (46.6%).

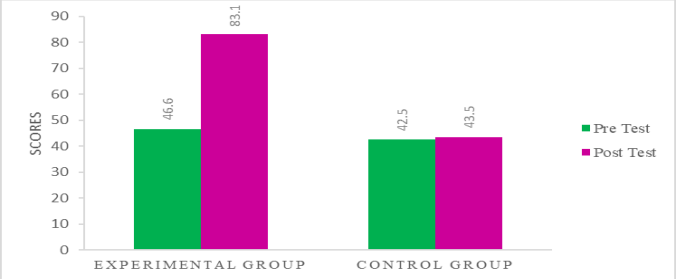

Fig 2: Pre and post-test scores of quality of life of participants in experimental and control group

Table 3: –Comparison of mean & standard deviation ofpre and post-test scores of the experimental group and the Quality of life of women with primaryinfertility

N=15+15=30

Fertiqol Scale	Group	Test	Mean	S.D	SE	Mean Difference	Statistical analysis
Emotional	Experimental	Pre Test	5.33	1.175	303	10.326	t=23.620 p=0.000*
		Post Test	14.80	1.207	.312		
Mind & Body	Experimental	Pre Test	6.07	1.486	.384	10.738	t=15.976 p=0.000*
		Post Test	15.53	1.187	.307		
Relational	Experimental	Pre Test	5.33	1.047	.270	9.776	t=20.917 p=0.000*
		Post Test	14.20	1.265	.327		
Social	Experimental	Pre Test	11.87	1.187	.307	3.960	t=9.025 p=0.000*
		Post Test	15.07	.799	.206		
Treatment Environment	Experimental	Pre Test	12.13	1.060	.274	2.776	t=4.404 p=0.001*
		Post Test	14.00	1.309	.338		
Treatment Tolerability	Experimental	Pre Test	5.93	1.163	.300	4.185	t=13.208 p=0.000*
		Post Test	9.53	640	.165		

Table: 3 depicts that there is statistically significant improvement in all aspects of quality of life, Emotional (t=23.620 p=0.000), Mind-(t=15.976 p=0.000*), Relational (t=20.917, p=0.000*), Social (3.960, t=9.025, p=0.000*), Treatment environment (2.776, t=4.404, p=0.001*), Treatment tolerability (t=13.208, p=0.000*) after the intervention at p <0.05

DISCUSSION

The study's results indicate a notable improvement in various aspects of quality of life following the intervention within the experimental group. Specifically, significant enhancements were observed in emotional well-being (t=23.620, p=0.000), mental health (t=15.976, p=0.000*), relational satisfaction (t=20.917, p=0.000*), social interactions (t=9.025, p=0.000*), treatment environment perception (t=4.404, p=0.001*), and treatment tolerability (t=13.208, p=0.000*) at a significance level of $p < 0.05$.

These findings echo those of a study conducted by Aulakh et al., focusing on the impact of nursing interventions, including meditation, progressive muscle relaxation exercises, and counseling, on lifestyle and dietary modifications among women undergoing infertility treatment. Their research revealed a marked improvement in marital relationships, with a mean difference in marital satisfaction of 4.633 (t29=10.640, p=0.001). Furthermore, the mean difference between the experimental and control groups was 3.867 (t58=4.215, p=0.001), indicating a statistically significant improvement at the 0.001 level. These findings underscore the importance of holistic interventions in addressing the multifaceted challenges

associated with infertility, particularly in the context of the post-COVID era, where such cases are on the rise.

In the wake of the COVID-19 pandemic, there has been a notable increase in infertility cases, further underscoring the significance of interventions aimed at improving the quality of life for affected individuals. The psychological toll of infertility, exacerbated by the stress and uncertainty brought about by the pandemic, highlights the urgent need for comprehensive support measures. The findings of our study, alongside those of Aulakh et al., emphasize the effectiveness of integrative approaches, encompassing physical, emotional, and relational dimensions, in addressing the complex needs of individuals experiencing infertility.

The observed improvements in emotional well-being, mental health, and relational satisfaction following the intervention are particularly noteworthy, as these areas are often profoundly affected by infertility. The implementation of aerobic exercises, coupled with counseling, not only fosters physical fitness but also promotes emotional resilience and strengthens interpersonal bonds. By enhancing treatment environment perception and tolerability, our intervention empowers individuals to navigate the challenges of infertility treatment with greater confidence and optimism.

Furthermore, the parallels between our study and that of Aulakh et al.[5-11] underscore the reproducibility and generalizability of our findings across different populations and intervention modalities. Both studies highlight the transformative potential of holistic interventions in improving overall well-being and marital satisfaction among individuals undergoing infertility treatment. As such, these findings have far-reaching implications for healthcare professionals, policymakers, and researchers seeking to address the burgeoning crisis of infertility in the post-COVID era.

Moving forward, it is imperative to continue exploring innovative approaches to infertility management that prioritize the holistic needs of affected individuals and couples. Integrating evidence-based interventions, such as aerobic exercises and counseling, into routine clinical practice can significantly enhance the effectiveness and inclusivity of infertility care. By fostering a supportive and empowering environment, we can empower individuals to confront infertility with resilience and hope, ultimately improving their quality of life and marital satisfaction in the face of adversity

CONCLUSION

The intervention involving aerobic exercises such as walking and jogging led to improved quality of life among infertile women in the experimental group. However, to validate and generalize these findings, further research with a larger sample size is warranted.

Conflict of Interest: Nil
Ethical issues addressed
No external financial aid

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REVIEW ARTICLE

MODULE FOR HEARTFULNESS RELAXATION AND MEDITATION TO IMPROVE THE QUALITY OF LIFE

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ABSTRACT:

Heartfulness Meditation and Relaxation on the effects of contemplative practices on cognitive function, well-being, and neurophysiology, it reduces stress and improves the Quality of Life.

Keywords:

Heartfulness Meditation**,** Relaxation**,** Quality of Life

INTRODUCTION:

Heartfulness is a contemplative tradition with a global presence that enables practitioners to experience the transcendence of individual human consciousness with the use of a few simple practices (Patel and Pollock, 2018). most research has focused on the effects of contemplative practices on cognitive function, well-being, and neurophysiology, largely without considering the philosophy or tradition from which the practices originate.

Heartfulness Meditation is designed to help practitioners regulate and relax the mind and expand consciousness, eventually leading to a permanently awakened state, not only during meditation but at all other times.

What is heartfulness meditation?

Heartfulness is a heart-centered approach to life, where you will ideally be able to live each moment by the heart. It is to live naturally, in tune with the noble qualities of a heart, enlightened and refined through spiritual practice.

Four steps :

1. Relax,
2. Meditate,
3. Rejuvenate/ **cleaning,**
4. Connect.

First, Relaxation. Heartfulness Relaxation is so simple that children of 5 years of age learn it and happily teach it to their parents. Yet it is so potent that it removes stress and tension from the body, calms the nervous system, and settles breathing, so that you feel deep relaxation. You may also feel some relief from many physical and mental ailments.

Second, Meditation. Meditation is a natural human pastime. When we practice meditation, we turn our attention inward to the center of our being, and at first, that is not so easy. We usually find it hard to go beyond the flurry of thoughts and feelings that arise when we close our eyes. Luckily, Heartfulness Meditation is supported by the ancient yogic technique of Pranahuti, which takes us beyond the mental level, allowing us to dive deeper into the heart from the outset. While we start with the thought that "the source of Light that is already present in my heart is attracting me from within," we soon go to a level where we experience the source of Light, and then further beyond that. We touch the center of our being where we find stillness, peace, and contentment.

Third, Cleaning. Imagine resting your mind in stillness, peace, joy, and love. Imagine having such clarity that you automatically make wise decisions without all the confusion and procrastination that generally accompany decision-making. Heartfulness Cleaning is the method that purifies the mind of all its complexities and heaviness, allowing you to feel light and carefree in your approach to life. It will simplify your world by detoxing your mind at the end of each day.

Fourth, Connect with your inner self. Heartfulness Connect allows you to connect with your inner self and listen to your heart's voice. You can then weave your destiny. It is like taking a dip into the source of life itself, and you will emerge refreshed and balanced. When you connect before sleeping at night, your sleep will be deep and refreshing, and every new day will start positively.

What are the 5 C's of mindfulness meditation?

1. Contentment,
2. Calm,
3. Compassion,
4. Courage,
5. Clarity,

were the foundation of our mental, emotional, and social intelligence.

Uses of Mindfulness Meditation

Mindfulness meditation is a form of meditation that focuses on the heart. Some immediate effects reported by practitioners include

- A sense of calm, relaxation, and increased awareness of one's emotions.
- It can also lead to reduced stress and anxiety,
- Improved concentration, and a greater sense of inner peace.

What is the relaxation?

It removes stress and tension from the body, calms the nervous system, and settles breathing,

Purpose of relaxation

- When we relax, the flow of blood increases around our body giving us more energy.
- It helps us to have a calmer and clearer mind which aids
  - Positive thinking,
  - Concentration,
  - Memory,
  - Decision-making.
- Relaxation slows our heart rate, reduces our blood pressure, and relieves tension.

Benefits of heartfulness relaxation

Heart-based meditation practice aimed at achieving a state of balance of mind. Participants in coping with workplace stress,

Decrease burnout,

Improve emotional wellness,

Increase telomere length.

Importance of relaxation

Relaxation keeps your heart healthier,

cuts stress,

Reduces muscle tension,

Improves brain function and memory,

helps you avoid depression, anxiety, and obesity.

It boosts your immune system and helps alleviate the symptoms of many medical and psychological disorders.

What are the effects of meditation and relaxation?

- Reduced stress
- Improve symptoms of stress-related conditions, including irritable bowel syndrome (IBS), post-traumatic stress disorder (PTSD), and fibromyalgia.
- Improved memory
- Better focus through regular meditation may increase memory and mental clarity.

Standard Guidelines for Mindfulness Relaxation and Meditation

Steps	Guidelines	Benefits
1.	Sit comfortably and close your eyes very softly and very gently.	It helps to prevent distraction.
2.	Let's begin with the toes	Wiggle your toes. Now feel them relax.
3.	Relax your ankles and feet.	Feel the energy move up from the earth. While it is moving upward, try to feel how the cells, the muscles, and the bones it covers are relaxing up your feet to your knees relaxing the legs.
4.	Relax your thighs	The energy moves up your legs relaxing them, Feel the lightness in relaxation.
5.	Relax your hips, stomach, and waist	Improve Relaxation
6.	Relax your back	From the top to the bottom the entire back is relaxed.
7.	Relax your chest and shoulders	Feel your shoulders simply melting away
8.	Relax your upper arms. Relax each muscle in your	

	forearms, your hands … right up to your fingertips.	Feel how your whole body is now completely relaxed.
9.	Relax the neck muscles	
10.	Move your awareness up to your face. Relax the jaws, mouth nose, eyes earlobes, facial muscles, and forehead to the top of your head.	
11.	Move your attention to your heart.	Rest there for a little while. Feel immersed in the love and light in your heart.
Remain still and quiet, and slowly become absorbed in yourself. Remain absorbed for as long as you want, until you feel ready to come out. And we have to meditate for 20 minutes or 30 minutes, whatever you can, whatever time you have available, you can do it. And you will feel it, in 20 minutes or 30 minutes when it ends on its own.		

Conclusion:

Heartfulness is a simple meditation method that has the potential to affect human beings at many different levels of their existence. Heartfulness Relaxation and Meditation reduce Stress, relax the mind, and improve the quality of life.

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